

**2015-1862**

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UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT

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MEDTRONIC, INC. & MEDTRONIC VASCULAR, INC.,

*Appellants,*

v.

LIFEPORT SCIENCES LLC,

*Appellee.*

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*Appeal from the United States Patent & Trademark Office, Patent Trial and  
Appeal Board in Case No. IPR2014-00288*

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**BRIEF OF APPELLANTS**

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September 25, 2015

## **CERTIFICATE OF INTEREST**

Counsel for Appellants Medtronic Inc. and Medtronic Vascular Inc. certifies the following:

1. The full name of every party or amicus who has been represented by me is:

Medtronic Inc. and Medtronic Vascular Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

Medtronic Inc. and Medtronic Vascular Inc.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Medtronic Vascular Inc. is a wholly owned subsidiary of Medtronic Inc.

Medtronic plc wholly owns and is the ultimate parent of Medtronic Inc. Medtronic plc is a publicly held company. No other publicly held company owns 10 percent or more of the stock of Medtronic plc.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Skadden, Arps, Slate, Meagher & Flom LLP (James J. Elacqua & Edward L. Tulin)

Date: September 25, 2015

/s/ James J. Elacqua

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## STATEMENT OF RELATED CASES

This appeal arises from the decision of the Patent Trial and Appeal Board ("PTAB") in the *inter partes* review of U.S. Patent No. 7,147,662 ("the '662 patent") in *Medtronic, Inc. v. Lifeport Sciences LLC*, No. IPR2014-00288 (P.T.A.B. Apr. 21, 2015) ("Final Written Decision"). This *inter partes* review was instituted in response to a petition filed by Medtronic Inc. and Medtronic Vascular Inc. (collectively, "Medtronic") against Patent Owner LifePort Sciences LLC ("LifePort"). No other appeal in or from the same *inter partes* review proceeding was previously before this or any other court.

The '662 patent is also the subject of a district court infringement case currently before the U.S. District Court for the District of Delaware: *LifePort Sciences LLC v. Medtronic Inc.*, No. 12-01793-GMS ("the Delaware Litigation"). The Delaware Litigation is stayed in its entirety pending the resolution of IPR2014-00288, through final appeal.

## **JURISDICTIONAL STATEMENT**

The PTAB had jurisdiction over Medtronic's petition for *inter partes* review of the '662 patent under 35 U.S.C. § 6(c). The PTAB issued a Final Written Decision on April 21, 2015. This Court has jurisdiction under 28 U.S.C. § 1295(a)(4)(A) and 35 U.S.C. § 329.

## STATEMENT OF ISSUES

1. Whether the PTAB committed an "analytical error," which is not entitled to deference, by concluding that the prior art does not expressly teach a "permanent curve," even though the prior art specifically shows the identical and unchanging curvature for multiple embodiments of hooks on an endoprosthesis.
2. Whether the PTAB committed legal error by effectively requiring extrinsic evidence regarding *in vivo* performance of an endoprosthesis when the intrinsic evidence specifically discloses a curve that is permanently maintained *in vivo*.
3. Whether the PTAB committed legal error by effectively requiring that the prior art disclose heat treatment for the hooks of an endoprosthesis even though (a) the construed claim does not include a limitation on how a "permanent curve" is created, and (b) the prior art combination specifically discloses one of the materials that LifePort itself contends can be used to make a curve "permanent."

## STATEMENT OF THE CASE

The '662 patent claims relate exclusively to a structural element that is among the most familiar and ubiquitous in existence: a hook. Specifically, the '662 patent is directed to an allegedly "improved" hook for fixation of endoluminal prostheses—including stents, grafts, and filters—to a vein, artery, or other lumen of the human body. The '662 patent claims are not directed to a new type of endoprosthesis, nor to a new way of delivering an endoprosthesis to a patient, nor to a new way of making an endoprosthesis, nor to a new type of hook for such a prosthesis. Instead, the '662 patent merely claims a hook that has a "permanent curve." As construed by the PTAB, this means that the hook must have "a preset curve that maintains a fixed arc throughout normal use regardless of what configuration the device is in." (A11.)

In its Final Written Decision, the PTAB focused exclusively on the question of whether the prior art, alone or in combination, discloses a "permanent curve." Medtronic put forth a prior art combination (White and Ostrovsky)<sup>1</sup> that unquestionably depicts and describes a hook on an endoprosthesis with a fixed, identical, unchanging arc in (a) the compressed configuration; (b) the expanded

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<sup>1</sup> As used herein, "White" refers to PCT International Publication No. WO 00/18322 and "Ostrovsky" refers to U.S. Patent No. 6,447,530. LifePort did not dispute that the combination of White & Ostrovsky teaches every other element of the '662 patent claims that were reviewed in light of this art. (See A178-97.)

configuration; (c) during the transition between the expanded and compressed configurations; (d) during *in vivo* deployment; and (e) in a catheter for either delivery or removal. The White-Ostrovsky endoprosthesis is depicted in a manner that is virtually identical to that shown in the '662 patent, is made of precisely the materials that the '662 patent discloses, and, like the '662 patent, is specifically described as providing secure and "permanent" implantation of an intraluminal device. (A278.) The PTAB improperly ignored these unequivocal teachings of the White-Ostrovsky combination, and imported limitations that are not found in the claims or claim construction. It was only through these clear factual and legal errors that the PTAB was able to incorrectly conclude that the White-Ostrovsky combination did not teach a hook with a "permanent curve."

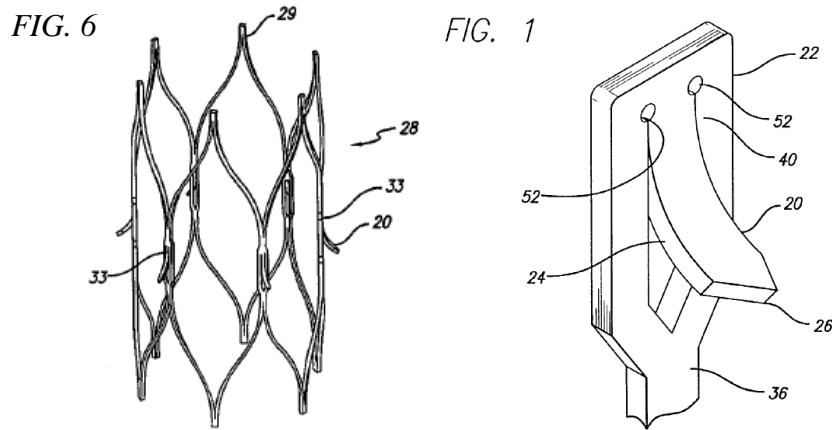
Because the PTAB overlooked the indisputable teachings of the White-Ostrovsky combination, which show an endoluminal prosthesis with a hook that has a "permanent curve," as the PTAB defined that term, the PTAB's determination of non-obviousness should be reversed and this case should be remanded for further proceedings.

## STATEMENT OF FACTS

### I. The '662 Patent

The '662 patent is entitled "Hook for Attaching to a Corporeal Lumen and Method of Manufacturing." It issued from U.S. Patent Appl. No. 10/326,719, which was filed on December 19, 2002, and claims ultimate priority to U.S. Patent Application No. 09/547,822, which was filed on April 11, 2000. The written description of the '662 patent spans less than six columns of text, much of which concerns unclaimed methods of manufacturing a hook for the endoprosthesis.

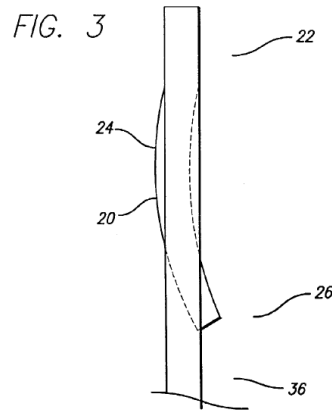
As its title suggests, the '662 patent is directed primarily to an allegedly "improved hook" that "provides for the attaching of endoluminal prosthesis within corporeal lumens." (A266, Abstract.) This hook is "integrally formed with [a] framing structure and is preset into an outward bend," such that it is "capable of impinging upon the corporeal lumen and thereby securing the prosthesis." (*Id.*) Figure 6 shows the conventional nature of the claimed hook **20** on an endoprosthesis **28**, while Figure 1 provides a close-up view of one embodiment of such a hook **20**:



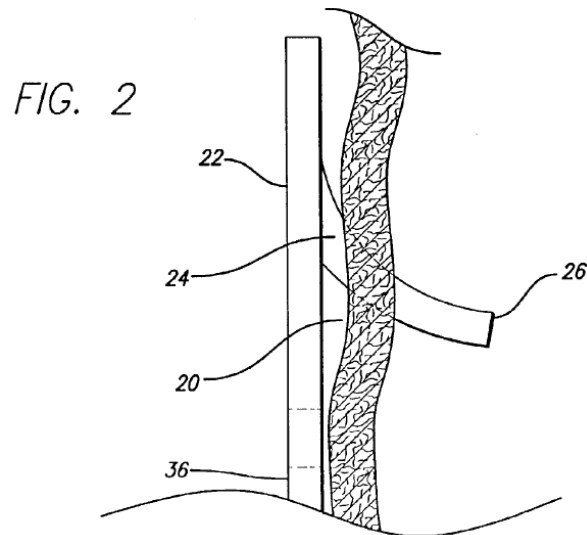
The hook **20** and frame **22** depicted above in Figure 1 are "typically formed of metal." (A275 at 4:50.) The '662 patent notes that "[b]iocompatible stainless steel and Nitinol (Nickel Titanium Alloy), are particularly suited for this purpose," but that other materials "such as ceramics and plastics may also perform adequately." (*Id.* at 4:51-54.)

In the "Summary of the Invention" section of the '662 patent, the allegedly improved endoprosthesis "hook is configured for intraluminal delivery within a catheter or capsule," so that it "may then be delivered to a diseased or damaged portion of a corporeal lumen such as an artery or vein." (A274 at 1:58-62.) The '662 patent employs well-known methods of delivering stents, grafts, and filters: in order to facilitate intraluminal delivery to a desired location *in vivo*, the hook **20** is compressed into "a very narrow cross section which facilitates loading the device into a catheter for delivery." (A275 at 3:35-37; *see also* A275 at 4:9-10 (noting that prior art "[e]ndoluminal devices are typically collapsed for

intraluminal delivery")) This "compressed configuration" is depicted in Figure 3 of the '662 patent:



Once the device has been delivered to the desired location, it can undergo a change from the above-depicted compressed configuration to an expanded configuration, so that the curved hook **20** becomes embedded in the body tissue, as shown below in Figure 2:



Although the '662 patent shows the hook **20** engaged in a body lumen, it does not show or discuss any of the forces that act upon the hook **20** *in vivo*.

Each of the claims of the '662 patent requires that the claimed hook have a "permanent curve."<sup>2</sup> Claim 1 of the '662 patent is representative:

1. A mechanism for securing an endoprosthesis within a corporeal lumen, the mechanism comprising:

a frame element with incisions formed therein, the frame element having a substantially tubular shape and lacking concentrically overlapping structure;

the incisions forming an elongated member having a pointed end, the elongated member being bounded by the frame element; and

*the elongated member bent away from said frame element wherein the elongate[d] member has a permanent curve.*

(A276 at 6:22-31 (emphasis added).) The other independent claims (10 and 16) similarly recite an endoluminal apparatus with one element that is permanently curved. (A276 at 6:53-61; A277 at 7:7-8:7.) The dependent claims of the '662 patent generally specify particular geometries for the claimed hook; for instance, claim 7 requires that the pointed end of the claimed "elongated member" has a "pointed end" with "at least one barb," while claim 15 requires that the point of the

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<sup>2</sup> The '662 patent uses slightly different terminology to describe the allegedly improved "hook"—it is sometimes referred to as an "attachment or anchoring element," a "protrusion, hook, barb," or an "elongated member." (A274 at 1:45-47.) Consistent with the approach of the '662 patent, the term "hook" will be used herein to encompass all of these terms. (*See, e.g.*, A274 at 1:55-58 ("In general, the present invention provides an improved attachment or anchoring element (which will referred to herein as a hook for convenience) for fixation of endoluminal prosthesis.").)

claimed connector "is formed in an arrowhead configuration." (*See* A276-77 at cls. 7, 15.)

All of the '662 patent claims are apparatus claims; no method claims or product-by-process claims appear in the '662 patent.

## **II. The Relevant Prior Art**

### **A. The Teachings of Ostrovsky**

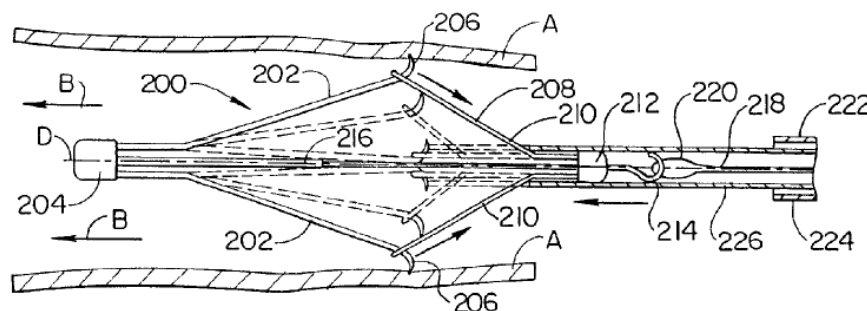
Ostrovsky is a U.S. patent entitled "Atraumatic Anchoring and Disengagement Mechanism for Permanent Implant Device." (A278.) It was filed on November 25, 1997, and issued on September 10, 2002. (*Id.*) There is no dispute that Ostrovsky constitutes prior art to the '662 patent under 35 U.S.C. § 102(e), and LifePort made no attempt to swear behind the priority date of Ostrovsky. (A181.) Ostrovsky was not before the examiner during prosecution of the '662 patent.

Ostrovsky describes a recoverable endoprosthesis with a "plurality of thrombosis filtering elements" including "shaped ends for engaging an inner lumen wall" that are "shaped in a predetermined manner." (A292 at 3:7-11.) Like the intraluminal devices described in the '662 patent, the Ostrovsky intraluminal device has two primary configurations: (1) a radially compressed configuration for both delivery and extraction/removal from the body; and (2) an expanded configuration in which the curved hooks are engaged with a body lumen. (*Id.* at 3:11-34.)

Ostrovsky teaches the use of a catheter to maintain the device in its compressed state for delivery to the site of deployment, and likewise teaches that the catheter is thereafter removed to allow the filter to be deployed in its expanded configuration. (A293 at 5:8-23; A279 at Fig. 1.) For removal of the filter, this process is reversed; the Ostrovsky device is first collapsed back into its compressed configuration, and then re-inserted into a "removal catheter." (A292-93 at 4:58-5:4; A289-90 at Figs. 29-35.) Ostrovsky illustrates these various configurations in Figures 33-35, in which the curved hooks **206** of Ostrovsky have been "sharpened and barbed to engage with the wall of [the] vessel." (A295 at 9:65-66.)

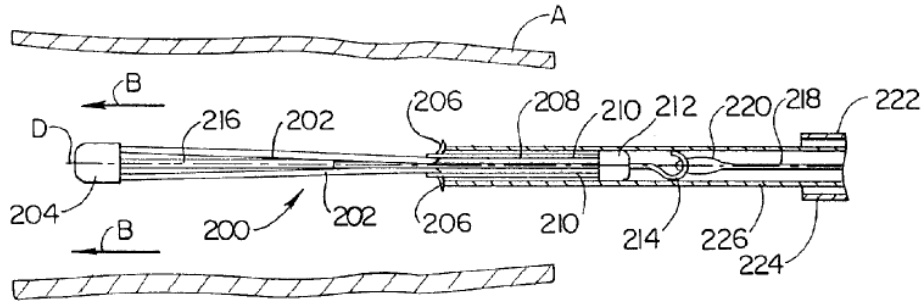
In Figure 33, a deployed Ostrovsky filter, which has curved hooks **206** engaged with the vessel lumen *in vivo*, is being prepared to be removed from the body through the use of retraction members **208**. Those retraction members **208** are used to pull the struts **202** of the filter from their expanded configuration back into the original, compressed state that the filter occupied when it was first deployed, as illustrated by the dotted lines in Figure 33:

**Fig.33**



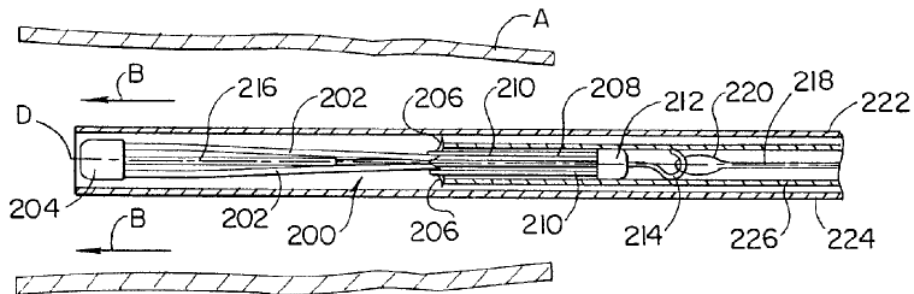
In Figure 34, this retraction process is complete, and the filter is being inserted into a catheter **222**, just like the one that was originally used to deliver the filter:

**Fig.34**



Finally, in Figure 35, the intraluminal device of Ostrovsky has been fully reinserted into the catheter **222**:

**Fig.35**



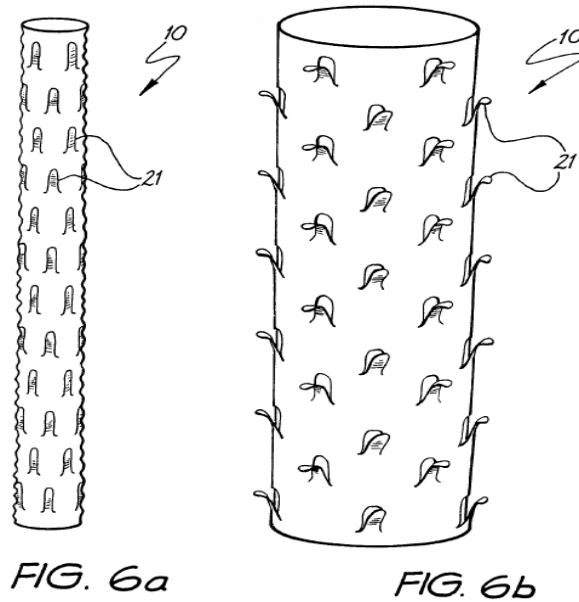
At all times during the entire sequence of events in Figures 33-35—*in vivo* deployment of the Ostrovsky device in the expanded state, transition of the Ostrovsky device from the expanded state to the compressed state, and insertion of the Ostrovsky device into a catheter—the curvature of the hooks **206** remains permanently and precisely the same.

Although Ostrovsky focuses on the use of engaging members/hooks in a vena cava filter, Ostrovsky also emphasizes that "[t]he anchoring device of the present application can be used with other devices such as stents [and] stent grafts." (A292 at 3:17-20.)

#### **B. The Teachings of White**

White is a PCT application entitled "Expanding Intraluminal Device," which was published on April 6, 2000. There is no dispute that White constitutes prior art to the '662 patent under 35 U.S.C. § 102(a), and LifePort made no attempt to swear behind the publication date of White. (A180.) White was not before the examiner during the prosecution of the '662 patent.

The intraluminal device described by White is intended for "use in the treatment of aneurysmal and stenotic disease." (A297, Abstract.) It has a tubular body, and at least one curved hook (referred to as an "engagement member") that is connected to or integral with a wall of that tubular body. (A300 at ll. 8-15.) Like the hooks of the '662 patent, these engagement members can be formed from a number of different materials, including Nitinol, stainless steel, or plastics. (A306 at ll. 31-36.) And like both the '662 patent and Ostrovsky, in order to insert and deploy the White device into a diseased lumen, it can assume both a radially compressed state as well as a radially expanded state. Exemplary embodiments of those compressed/expanded configurations are depicted in Figures 6a and 6b:



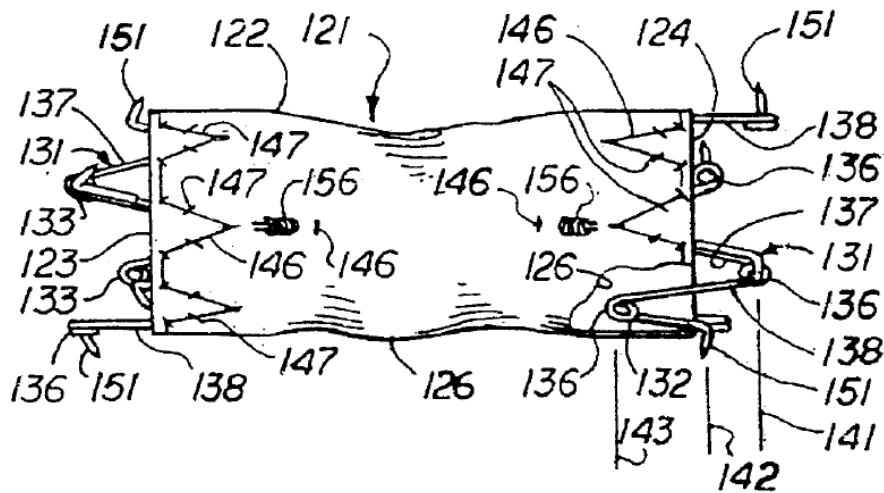
(A326.) Like the '662 patent, White teaches that when the tubular intraluminal device body is in the radially compressed state, the curved engagement members/hooks "may project inwardly, within the lumen of the device body."

(A307 at ll. 27-33.) In such embodiments, the engagement members are never "flat"; they maintain some curvature in both configurations. (*Id.*) Once the device transitions from its radially compressed state to its radially expanded state, the engagement members/hooks "come in contact with the inside surface of the vessel wall and then [become] at least part embedded in the vessel wall," which is designed to "assist in resisting any tendency for the device to move longitudinally within the vessel following deployment of the invention." (A311 at ll. 20-24; *see also* A305 at ll. 34-36 ("The provision of such engagement members will be to act as an attachment, hook or anchor to prevent the device from moving longitudinally within the vessel following deployment of the invention . . .").)

### C. The Teachings of Lazarus

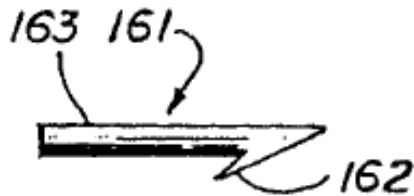
U.S. Patent No. 5,562,728 ("Lazarus") is entitled "Endovascular Grafting Apparatus, System and Method and Devices for Use Therewith," and issued on October 8, 1996. There is no dispute that Lazarus constitutes prior art to the '662 patent under 35 U.S.C. § 102(b). (*See* A197-207.) Lazarus was not before the examiner during the prosecution of the '662 patent.

Lazarus teaches a tubular endovascular stent-graft that can be inserted percutaneously. An exemplary embodiment of the Lazarus stent-graft **121** is shown in Fig. 10, which is reproduced below:

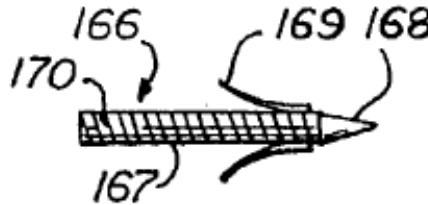


Lazarus teaches that its claimed stent-graft can be equipped with hooks or barbs to attach to the vessel wall "[i]n order to ensure that the graft **121** will not become dislodged after it has been implanted." (A340 at 10:23-24; Figs. 12-13.) Lazarus also teaches a number of different embodiments for the hooks, including

the barbed and arrowhead configurations shown in Figures 12 & 13, reproduced below:



***Fig. 12***



***Fig. 13***

### **III. The PTAB Proceedings**

#### **A. The Institution of *Inter Partes* Review**

On December 20, 2013, Medtronic filed a petition for *inter partes* review of the '662 patent. Medtronic filed a corrected petition on January 14, 2014, seeking review of the claims of the '662 patent on eight separate grounds (one ground of anticipation and seven grounds of obviousness). (A40-105.) Patent Owner LifePort did not file a preliminary response.

On June 25, 2014, the PTAB instituted *inter partes* review of claims 1-5, 7-13, 15, and 16 of the '662 patent. Specifically, the PTAB instituted review of whether claims 1-3, 5, 9-13, and 16 are anticipated by U.S. Patent No. 5,108,418 ("Lefebvre") and whether claims 7, 8, and 15 are obvious in light of the combination of Lefebvre with U.S. Patent No. 5,562,728 ("Lazarus").<sup>3</sup> In addition,

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<sup>3</sup> The PTAB's conclusions regarding (1) Lefebvre and (2) Lefebvre in combination with Lazarus, are not at issue in this appeal.

the PTAB instituted review of claims 1-4, 8-12, and 16 in light of the combination of White and Ostrovsky, and claims 7 and 15 in light of the combination of White, Ostrovsky, and Lazarus. In the Institution Decision, the PTAB construed only a single term: "permanent curve." Although this term does not appear anywhere in the patent specification, it is found in each and every one of the '662 patent claims. Initially, the PTAB determined that the broadest reasonable construction in light of the specification for the term "permanent curve" is "a preset curve that maintains a permanent curve regardless of what configuration the device is in." (A114.)

## **B. The PTAB Trial & Final Written Decision**

On February 15, 2015, the PTAB heard oral argument on Medtronic's petition for *inter partes* review of the '662 patent. (A211-265.) On April 21, 2015, the PTAB issued its Final Written Decision, in which it erroneously concluded that, under the PTAB's revised interpretation of the term "permanent curve," Medtronic had not proven by a preponderance of the evidence that the prior art taught this claim element.

### **1. Claim Construction**

Although LifePort and Medtronic both initially agreed that the broadest reasonable construction of the term "permanent curve" was "a preset curve that maintains a permanent curve regardless of what configuration the device is in," it became clear during the course of the proceedings that the parties differed on the

appropriate interpretation of that construction. In particular, "[t]he parties disagree[d] . . . as to whether . . . a permanent curve encompasses a . . . member that maintains some degree of curvature—even though the arc of the curve may change due to compressive forces—or whether it more narrowly demands a fixed arc that does not vary during use." (A8.) Medtronic argued that the former interpretation was correct, while LifePort argued that the latter interpretation should apply. (A218 at ll. 17-22; A219 at ll. 3-15; A234 at ll. 10-21.)

Under Medtronic's interpretation, a prior art reference that taught an endoprosthetic hook that was always curved in all of its configurations—even if that curvature changed slightly—would fall within the scope of the claimed "permanent curve." (A217 at ll. 21-22; A219 at ll. 8-12.) Medtronic argued that this interpretation was supported by the grammatical structure of the PTAB's initial construction and the prosecution history. (A217 at l. 19–A219 at l. 17.) There was no dispute that the prior art taught hooks that were always curved regardless of the configuration of the device—the only dispute was whether the prior art taught that the curvature had precisely the same arc in all configurations. (A220 at ll. 1-6.) In contrast, "LifePort's broadest reasonable interpretation of permanent curve . . . requires that 'the curve of the elongated member/hook/protrusion must be identical in all configurations of the device, and at all times.'" (A9 (citation omitted).) As such, "[a]ny temporary change to the curvature would mean that it is not

permanent, and would fall outside of the scope of the claims,'" thus excluding "'a curve that is deformed into a flattened or different curvature during deployment, and that elastically returns to a memorized curvature.'" (*Id.* (citation omitted) (noting that LifePort's position was that hooks that "resiliently return to a memorized shape embody *the opposite* of a permanent curve").)

The PTAB agreed with LifePort's narrower interpretation, and rejected Medtronic's broader interpretation.<sup>4</sup> The PTAB then refined its construction of "'permanent curve'" to be "'a preset curve that maintains *a fixed arc* throughout normal use regardless of what configuration the device is in.'" (*Id.* (emphasis added).)

## 2. The PTAB's Analysis of the Relevant Prior Art

The majority of the prior art analysis in the PTAB's Final Written Decision deals with references that are not at issue in this appeal. (*See* A12-23 (discussing Lefebvre and Lazarus).) Indeed, the PTAB devotes the smallest portion of its

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<sup>4</sup> Although, as discussed above, the PTAB rejected Medtronic's interpretation of "permanent curve," Medtronic is not challenging the PTAB's revised construction in this appeal. To the extent that the claim construction is altered during the course of this appeal, this case must be remanded to allow the PTAB the first opportunity to consider the impact of any new construction on all the instituted grounds from this proceeding. *See, e.g., Electro Scientific Indus., Inc. v. Dynamic Details, Inc.*, 307 F.3d 1343, 1350 (Fed. Cir. 2002) (noting that "a change in the claim construction at the appellate level generally necessitates a remand . . . to resolve any new factual issues raised by the new claim construction").

analysis to Ostrovsky—a reference that clearly teaches and depicts a permanently curved hook on an endoprosthesis. (A28-32.)

The PTAB did consider Figures 33 and 34 from Ostrovsky, and acknowledged that Medtronic contended that those figures taught a permanent curve because the pointed hooks **206** of Ostrovsky "'maintain an identical curve in each state.'" (A31 (citation omitted).) However, the PTAB performed absolutely no analysis of what Figures 33 and 34 (and the accompanying written description) from Ostrovsky actually taught. (*Id.* at A31-32.) The PTAB did not compare the arc of curvature for the hook **206** in its deployed *in vivo* configuration to the curvature of the hook **206** in its radially compressed configuration both inside and outside of its catheter—even though all of those configurations were explicitly described in the Ostrovsky specification. (*Id.*) Instead of analyzing the actual intrinsic teachings of Ostrovsky, the PTAB instead criticized Medtronic for failing to provide extrinsic evidence relating to unclaimed limitations that do not appear in the PTAB's revised claim construction. (*Id.*) In particular, the PTAB criticized Medtronic for failing to address whether Ostrovsky provides a method for "*the generation of a permanent curve.*" (A32 (first emphasis added).) The PTAB cited no claim limitation or portion of its claim construction that required certain method steps be performed to "generat[e]" a permanent curve. (*Id.*)

In addition, the PTAB criticized Medtronic for failing to perform an extrinsic analysis of any "forces acting upon the hook-like elements 206 when the Ostrovsky device is deployed in normal use." (A32.) But the PTAB overlooked that the intrinsic evidence already accounts for these forces. Ostrovsky shows the forces acting on its device from the flow of blood in the direction of **arrow B**, from the pressure of the retraction members **208**, and from the catheter **222**—but the PTAB did not assess the curvature of the hook **206** shown under the influence of these depicted and described forces. (A31-32.) Had the PTAB done so, it would have seen that the hook **206** has a fixed arc that is maintained throughout normal use: when it is subject to forces while embedded in the vessel, when it is transitioning between expanded and compressed configurations, and when it is in the catheter. (A290, Figs. 33-35.) This is precisely what the PTAB's claim construction required in order for a "permanent curve" to be found.

LifePort never argued that the combination of White & Ostrovsky lacked any element recited in 1-4, 8-12, and 16 of the '662 patent other than the "permanent curve,"<sup>5</sup> and thus the PTAB limited its analysis in the Final Written Decision to this claim limitation. Similarly, LifePort never argued that the

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<sup>5</sup> The only other claim limitation that LifePort addressed in its Response was the "permanent bend" recited in claim 10 of the '662 patent. However, LifePort made clear that the bases for this argument were the same "reasons articulated . . . with respect to the 'permanent curve' element of claim 10." (A194.)

combination of White, Ostrovsky, and Lazarus lacked any element recited in claims 7 and 15 of the '662 patent, other than the "permanent curve" limitation that was part of these dependent claims by virtue of its recitation in their respective independent claims. If the Federal Circuit concludes that White & Ostrovsky do in fact disclose a permanent curve, the only question remaining is whether there would have been a reason to combine the teachings of these references, all of which were directed to the same problem of preventing unwanted migration of an endoprosthesis.

### **SUMMARY OF ARGUMENT**

The PTAB performed an incomplete and analytically erroneous review of the combination of White and Ostrovsky, which improperly led the PTAB to conclude that this combination does not expressly teach a "permanent curve." This conclusion is directly at odds with the intrinsic teachings of White and Ostrovsky, and resulted from three key errors.

First, the PTAB overlooked that Ostrovsky explicitly depicts hooks with a preset curve that maintains its fixed, unchanging arc in the deployed, *in vivo* configuration; in the compressed configuration both inside of and outside the catheter; and during the transition between configurations—in other words, throughout its normal use. (*See e.g.*, A290, Figs. 33-35.) That is all that the PTAB's claim construction requires. (A11.) Because the PTAB's conclusion was

the result of analytical defects in the PTAB's review of the prior art, it is not entitled to deference. *See Smith & Nephew, Inc. v. Rea*, 721 F.3d 1371, 1380 (Fed. Cir. 2013). Even if its conclusions are characterized as resulting from factual errors (as opposed to analytical errors), the intrinsic disclosure of Ostrovsky is directly at odds with the PTAB's conclusions, and thus those conclusions are not supported by substantial evidence.

Second, the PTAB committed legal error by effectively requiring extrinsic analysis of the *in vivo* forces that the Ostrovsky endoprosthesis experiences after deployment. But this sort of extrinsic analysis is not required because the PTAB did not need to look beyond the four corners of Ostrovsky. Ostrovsky not only depicts and acknowledges the *in vivo* forces acting on the Ostrovsky device, but it also teaches that, despite these forces, the curved hooks of its endoprosthesis maintain identically fixed curvature. (*See* A290, Figs. 33-35; A295 at 9:58-61, 10:30-56.)

Third, the PTAB committed legal error by effectively requiring that the combination of White and Ostrovsky disclose heat treatment for Ostrovsky's endoprosthetic hooks. All of the claims of the '662 patent are apparatus claims—not method claims and not product-by-process claims. The PTAB's construction for "permanent curve" does not require any particular method of making a permanent curve. The only question that the PTAB should have considered when

assessing whether the hooks of Ostrovsky are permanently curved is whether those hooks "maintain[] a fixed arc throughout normal use"—which, in the case of Figures 33-35 of Ostrovsky, they indisputably do. Indeed, the Figures of Ostrovsky are virtually identical to the only alleged depiction of a permanent curve that the '662 patent provides. (*Compare* A290, Fig. 33 *with* A268-69, Figs. 2-3.) In addition, the PTAB overlooked that, even if a methodological limitation on how to create a "fixed arc" was imported into the claims (which it should not be), White specifically discloses a "plastic" material that the '662 patent teaches can be used to create a "permanent curve" *without needing any heat treatment*. (A306 at ll. 34-36.)

Because of the foregoing errors of fact and law, the PTAB's determination that the combination of White and Ostrovsky does not teach a permanent curve is at odds with the intrinsic evidence, and should be reversed.

## **ARGUMENT**

### **I. STANDARD OF REVIEW**

Obviousness under Section 103 is a question of law based on underlying factual findings. *In re Baxter Int'l, Inc.*, 678 F.3d 1357, 1361 (Fed. Cir. 2012). The Federal Circuit reviews the ultimate determination of obviousness *de novo*, and reviews the PTAB's underlying factual findings for substantial evidence. *In re Patel*, 566 F. App'x 1005, 1008 (Fed. Cir. 2014).

When the PTAB makes an analytical error in reviewing the prior art, the PTAB is not entitled to deference under the "substantial evidence" standard. *See Smith & Nephew, Inc.*, 721 F.3d at 1380 (determining that although "'substantial evidence' standard of review requires a deferential approach to the Board's findings," such deference is unwarranted where decision "was mainly the result of . . . analytical errors," and where the facts are essentially not in dispute (citation omitted)).

Even if the PTAB's determinations are characterized as factual, rather than analytical, they must be reversed if they are unsupported by substantial evidence. The substantial evidence standard is satisfied if and only if "a reasonable fact finder could have arrived at the [PTAB's] decision," and this standard is considered "to be a less deferential review standard than arbitrary, capricious." *In re Gartside*, 203 F.3d 1305, 1312 (Fed. Cir. 2000) (internal quotations omitted); *see also In re Huai-Hung Kao*, 639 F.3d 1057, 1065 (Fed. Cir. 2011) (the substantial evidence standard is not satisfied when the PTAB used "erroneous reasoning in making the factual determinations"); *Falkner v. Inglis*, 448 F.3d 1357, 1363 (Fed. Cir. 2006) (holding that substantial evidence review requires examining the record as a whole, including evidence supporting and detracting from the decision that has been appealed).

**II. THE PTAB COMMITTED AN ANALYTICAL ERROR WHEN IT INCORRECTLY DETERMINED THAT WHITE & OSTROVSKY DO NOT DISCLOSE A "PERMANENT CURVE"**

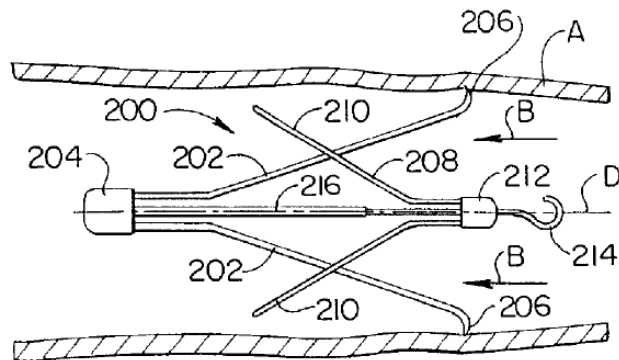
**A. Ostrovsky Teaches "A Preset Curve That Maintains A Fixed Arc Throughout Normal Use Regardless of What Configuration The Device Is In"**

The PTAB's revised construction for "permanent curve" contains two requirements: (1) that the curve be "preset" and (2) that the curve "maintains a fixed arc." As for the first requirement of the construction, Ostrovsky teaches that the elements of its endoprosthetic device, including the curved hooks "for engaging the inner wall of the lumen" are "shaped in a 'predetermined'" or preset manner. (A292 at 3:7-11.) Neither LifePort nor the PTAB cited any evidence to contradict this clear teaching of Ostrovsky.

Instead, the focus of both LifePort and the PTAB was on the second portion of the construction for "permanent curve," and whether the preset curve of the Ostrovsky hook "maintains a fixed arc throughout normal use regardless of what configuration the device is in." No reasonable factfinder could view Figures 33-35 of Ostrovsky, and their accompanying text, and conclude anything but that the hook **206** of Ostrovsky has a single, fixed arc of curvature that is present throughout normal use regardless of the device configuration. The PTAB's conclusion to the contrary is not merely unsupported by substantial evidence; it is directly at odds with the unmistakable and unequivocal teachings of Ostrovsky.

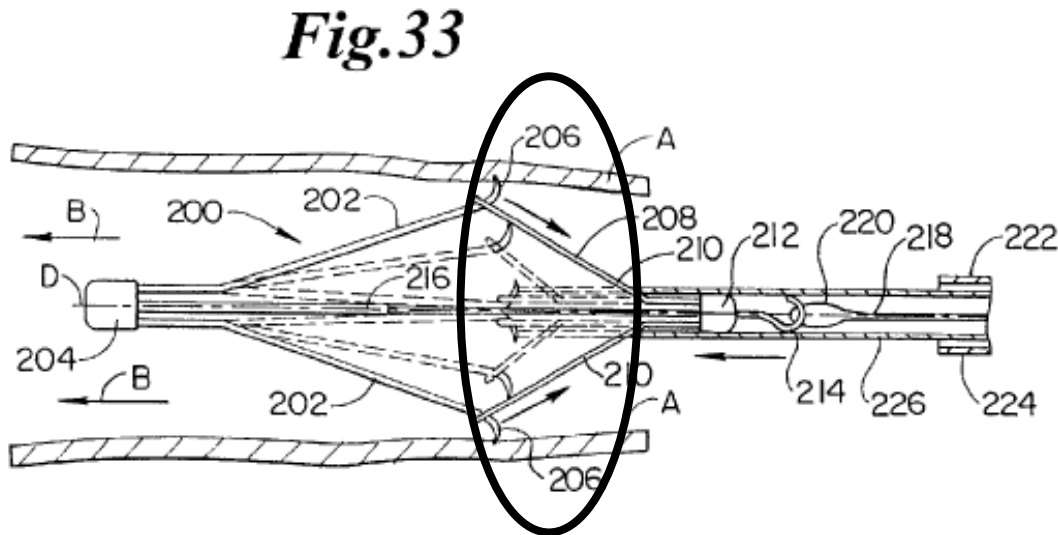
The Ostrovsky device is specifically designed to be delivered in a compressed state in a catheter to a deployment site, transition to an expanded state by which it engages with the vessel lumen at the deployment site, and then return to its compressed state for removal. In each of these configurations, the hook **206** has the same fixed, "predetermined" arc of curvature. (A292 at 3:7-11.) The endoprosthesis of **Figure 33** is shown in its *in vivo*, expanded, deployed configuration in **Figure 29**:

*Fig. 29*

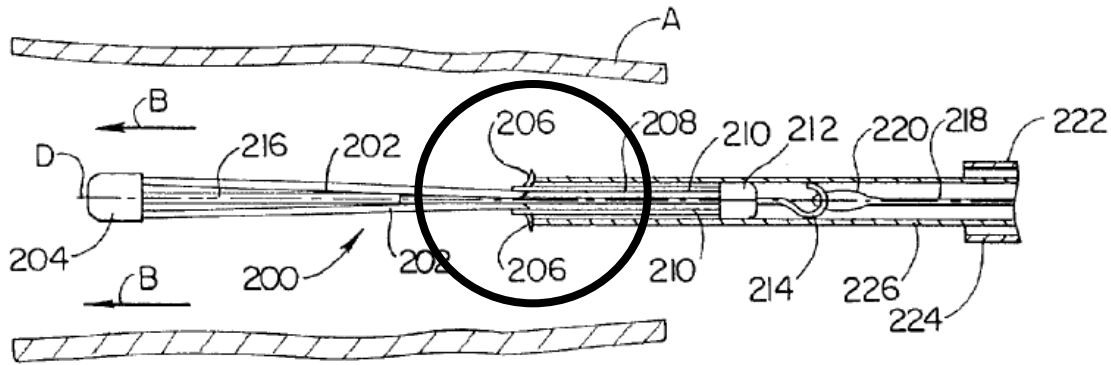


In the above figure, the blood flowing "in vessel A is shown in the direction indicated by arrows B." (A295 at 9:60-62.) This device also has "strut retraction members **208**," with a plurality of retraction loops **210**, which are designed to allow the filter to revert back to its compressed configuration by pulling the struts into their original position. (*Id.* at 10:1-5.) This occurs when the "retraction member **208** is being pulled in the first direction such that loops **210** are advancing

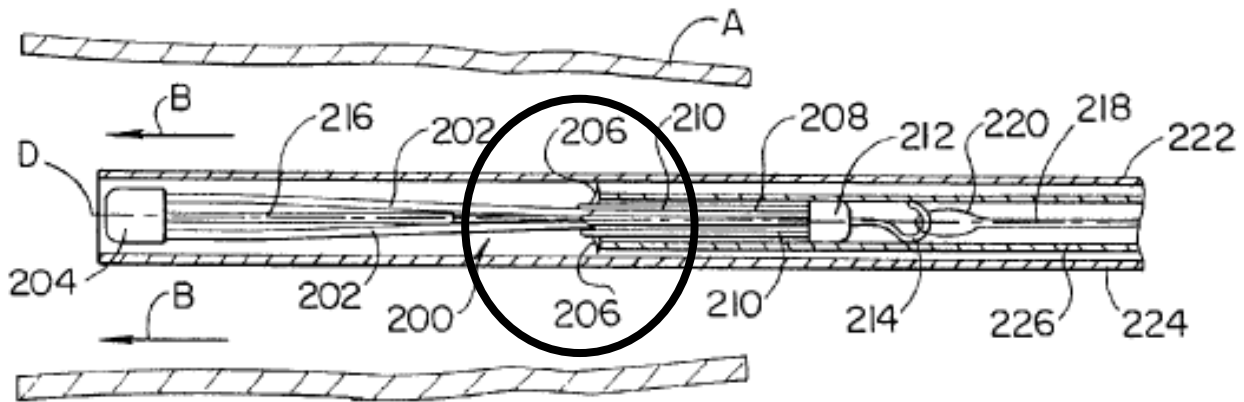
along and engaging struts **202**," (A295 at 10:30-35), as shown in Figure 33 (with the hooks **206** circled):



(A290, Fig. 33 (annotation added).) According to Ostrovsky, "Fig. **33** is a side view of filter **200** of Fig. **29** wherein . . . [i]n dashed lines, . . . struts **202** are brought from a first position engaging the walls of vessel A to a second position adjacent axis D of filter **200**." (A295 at 10:33-39.) In other words, the filter shown in Figure 33 is the identical filter that is shown in Figure 29; Figure 29 shows the filter **200** *in vivo* performing its filtering function, while Figure 33 shows filter **200** *in vivo* having completed its filtering function and being prepared for removal. (*Id.*) Figure 34 reproduces the final position of the struts **200** as part of this removal process in their "second position" that is generally parallel to longitudinal axis D (with the hooks **206** circled):

**Fig.34**

(A290, Fig. 34 (annotation added).) Finally the "filter **200** has been withdrawn into outer tube **224** of catheter **222**," and could now be "removed from the patient" (A295 at 10:44-48), as shown below:

**Fig.35**

(A290, Fig. 35 (annotation added).)

At each step, despite the change to the configuration of the struts (whereby the bend of struts **202** changes relative to the longitudinal axis D), and despite the various forces acting on the Ostrovsky device at each step (including the flow of

blood in the direction of **arrow B**, the forces from the **vessel wall A**, and the forces from the retraction members **208**, the arc of hooks **206** (highlighted above in the annotations) is fixed and unchanging. (A290, Figs. 33-35.) Although Ostrovsky does not depict the original deployment of filter **200**, it makes clear that "performing the steps of removal process [shown in Figures 33-35] in reverse would provide a method of placing filter **200** in vessel A as shown in Fig. **29**." (A295 at 10:49-51.) Thus, Figures 33-35 teach a fixed and unchanging curve for hooks **206** both during of deployment (and in all associated configurations), and during retraction (and in all associated configurations).

Tellingly, LifePort *did not even address* Figures 33-35 of Ostrovsky in the Patent Owner's Response. (*See* A145-210.) This is despite the fact that the PTAB's Institution Decision specifically discussed Medtronic's contentions that those Figures teach a permanent curve. (A128-130.) In particular, the PTAB noted that "Petitioner contends Ostrovsky's 'hook-like elements remain in their *permanently curved* configuration,' even if the configuration of the filter changes for deployment or removal," as shown in Figure 33 and Figure 34. (A130 (emphasis added).) At no time has LifePort provided any evidence or argument that the arc of curvature of hooks **206** in Figures 33-35 is not identical. Indeed, LifePort specifically conceded that Ostrovsky "shows devices with outwardly pointed protrusions" in the "compressed state," as opposed to a device where those

protrusions change shape and assume a flat or differently curved state. (A193 (emphasis omitted).) The "outwardly pointed protrusions" that LifePort identified are "outwardly pointed" in the same way in both the compressed and expanded configurations of Ostrovsky. (A290, Figs. 33-35.)

Moreover, the relevant teachings of a fixed arc curve in Figures 33-35 of Ostrovsky are identical to those in Figures 2-3 of the '662 patent. During oral argument before the PTAB, LifePort cited Figures 2 and 3 of the '662 patent as illustrating a permanent curve because it contended that "[t]he curve is the same in each configuration of the device." (A233 at ll. 9-11; A246 at ll. 12-20.) The '662 patent does not illustrate nor describe the curve of the claimed hooks in all of the configurations—for instance, it does not show when the device is in the catheter for *in vivo* delivery, or when the device is being removed from the catheter for deployment (both of which *are* taught and illustrated with an unchanging arc of curvature in Ostrovsky). Notwithstanding the limited nature of the disclosure in the '662 patent, a side-by-side comparison of the Ostrovsky hooks with those that LifePort contends are evidence of a permanent curve in the '662 patent shows that Ostrovsky's disclosure is precisely the same as that of the '662 patent in this regard.

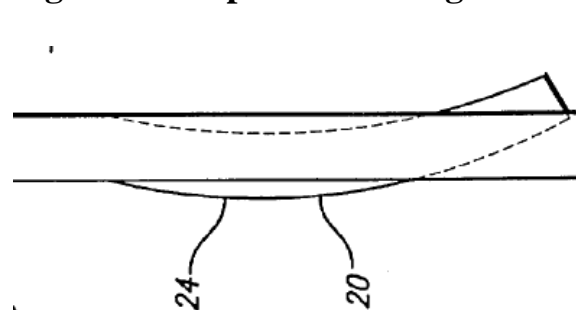
As shown below, in Figure 35 of Ostrovsky, the compressed configuration of the endoprosthesis in a catheter—either for deployment or for removal—is taught. (A295 at 10:44-51.) In Figure 3 of the '662 patent, the "compressed

configuration" of the endoprosthesis is likewise taught, which also "provides a very narrow cross section which facilitates loading the device into a catheter." (A275 at 3:35-37.) A side-by-side comparison of these figures is shown below:

**Close-up of Hook 206 of Ostrovsky  
Fig. 35 in Compressed Configuration**

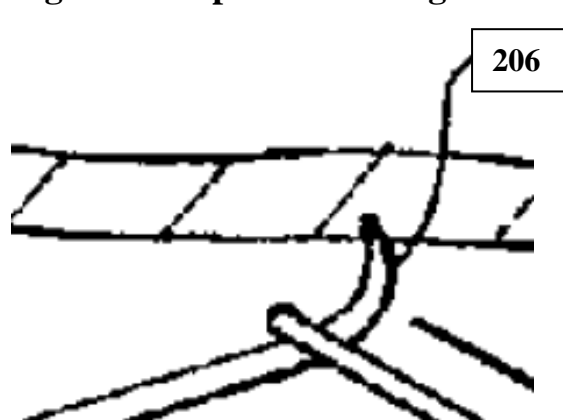


**Close-up of Hook 20 of '662 Patent  
Fig. 3 in Compressed Configuration**

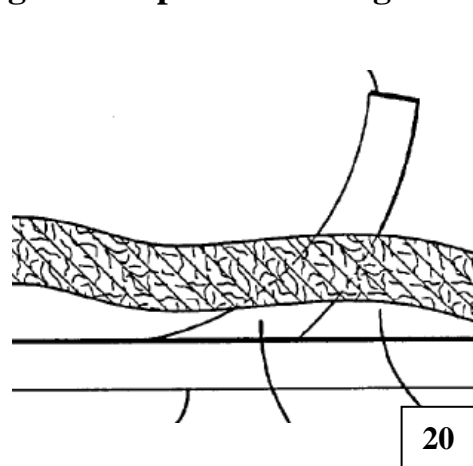


Then, in Figure 33 of Ostrovsky, the endoprosthesis changes to its expanded configuration—but with the hook **206** shown with *exactly the same preset, fixed arc of curvature*. Similarly, in Figure 2 of the '662 patent, the endoprosthesis has changed to its expanded configuration, while maintaining what LifePort contends is a constant arc of curvature, as illustrated below:

**Close-up of Hook 206 of Ostrovsky  
Fig. 33 in Expanded Configuration**



**Close-up of Hook 20 of '662 Patent  
Fig. 2 in Expanded Configuration**



LifePort has already represented to the PTAB that Figures 2 and 3 of the '662 patent depict a "permanent curve." (A233 at ll. 9-11; A246 at ll. 12-20.) Based on that representation, there can be no question that Figures 33 and 35 of Ostrovsky teach a "permanent curve."

The PTAB's conclusion that Ostrovsky fails to show a "permanent curve" is therefore at odds both with the explicit teachings of Ostrovsky, and with LifePort's own interpretation of what constitutes a permanent curve. Whether this error is characterized as analytical or factual, no reasonable review of Ostrovsky could lead to such a determination, and it should be reversed. *See, e.g., Boston Scientific Scimed, Inc. v. Cordis Corp.*, 554 F.3d 982, 989-91 (Fed. Cir. 2009) (reversing the denial of a motion for JMOL of obviousness of a patent directed to intraluminal stents as unsupported by substantial evidence in light of a prior art patent taught the relevant claim limitations in two figures).

**B. Because of the Clear Teachings of Ostrovsky, No Extrinsic Evidence of *In Vivo* Analysis Was Required**

As the foregoing discussion demonstrates, the curved hook **206** of Ostrovsky has precisely the same arc of curvature whether it is in a catheter, deployed *in vivo* and engaged with a vessel lumen, or being removed from the lumen. Thus, it was error for the PTAB to conclude that extrinsic evidence regarding *in vivo* performance of Ostrovsky was necessary to show that this reference teaches a permanent curve. Specifically, the PTAB improperly relied on Medtronic's alleged

"failure to address the forces acting on any part of an Ostrovsky device" as a basis for its conclusion that "the evidence of record [was] insufficient to demonstrate that Ostrovsky maintains a permanent curve." (A32.)

As an initial matter, the '662 patent does not disclose, depict, or discuss any of the forces that act upon the claimed hooks *in vivo*. In contrast to this dearth of disclosure in the '662 patent, the PTAB correctly noted that "as shown in Ostrovsky Figure 33 . . . , hook-like elements 206 are anchored in the wall of blood vessel A as blood flows through the filter in the direction of arrows B," and thus that there were "forces acting upon the hook-like elements 206 when the Ostrovsky device is deployed in normal use." (*Id.*) But the PTAB overlooked that *Ostrovsky itself* identified and acknowledged these forces, and yet despite their effects, the arc of curvature of hook 206 is shown to be precisely the same in all of its configuration, whether engaged with the blood vessel or not. (A290, Figs. 33-35.) As such, Ostrovsky itself has already taken these various forces into account, and notwithstanding them, the curvature of that hook is never altered, is never flattened, is never anything other than the same fixed arc. The intrinsic record could not be any clearer. But Ostrovsky's teachings extend even further, by showing the hook **206** subject to (a) forces from blood flow B, (b) forces from the vessel A, (c) forces from retraction of the device—thus demonstrating that none of

these forces, alone or in the aggregate, is sufficient to alter the arc of curvature for hook **206**.

Given these teachings, it was completely improper for the PTAB to have essentially second-guessed the unequivocal intrinsic disclosure of Ostrovsky, and required extrinsic evidence to supplement what was already a clear teaching of each and every element of what constitutes a "permanent curve."

**C. The PTAB Misapplied Its Own Claim Construction and Imported Unclaimed Limitations Relating to How the Permanent Curve Is Made As Part of Its Analysis of Ostrovsky**

The only way that the PTAB was able to reach its conclusion that Ostrovsky does not disclose a permanent curve was to improperly alter its claim construction analysis to import two unclaimed limitations: (1) that the permanent curve must be "generat[ed]" or manufactured through heat treatment; and (2) that the permanent curve must be made of Nitinol. (A31-32.) Neither of these limitations should have been included as part of the PTAB's analysis, and they represent a wholesale rewriting of both the claim language and the PTAB's own construction. That said, even if White and Ostrovsky must teach the use of a particular material for creating a permanent curve, they satisfy that standard.

**1. Neither the Claims of the '662 Patent Nor the PTAB's Claim Construction Require Any Particular Method of Making a "Permanent Curve"**

All of the claims of the '662 patent are apparatus claims; none of them claim any particular method of manufacturing the claimed apparatus, and none of them are product-by-process claims.<sup>6</sup> This is especially true for the limitations directed to the "permanent curve," all of which simply claim an element "having" or that "has" a "permanent curve," as shown below:

1. A mechanism for securing an endoprosthesis within a corporeal lumen, the mechanism comprising . . . an elongated member . . . , wherein the elongate[d] member ***has*** a permanent curve.

10. A connector for fastening a device to corporeal tissues, said connector comprising . . . a hook having two sides and a point . . . , and said hook ***having*** a permanent bend that forms a permanent curve.

16. An endoluminal prosthesis, comprising . . . at least one protrusion . . . , wherein the at least one protrusion ***has*** a permanent curve.

(A276-77, cls. 1, 10, 16 (emphasis added).) Moreover, the PTAB's claim construction does not require that a "permanent curve" be created using any particular methodology—it instead requires only a "fixed arc" that is present "regardless of what configuration the device is in." (A11 (citation omitted).) It was therefore error for the PTAB to have concluded that Ostrovsky does not disclose a permanent curve in part because Medtronic allegedly did not "explain how the reference teaches the *generation of a permanent curve*, as is taught, for

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<sup>6</sup> LifePort never argued to the PTAB that the claims should be treated as product-by-process claims.

example at column 6, lines 1-4, of the '662 patent (heating a Nitinol hook and frame combination 'at 550° C. for ten minutes')." (A32 (emphasis added).) LifePort does not claim to have invented the concept of heat treatment for endoprotheses, and LifePort never argued that it had come up with a novel method for the generation of a fixed arc of curvature—instead, LifePort has claimed only the presence of a permanent curve on an endoluminal prosthesis, wherein that curve remains fixed in all of its normal use configurations. Whether the Ostrovsky hook **206** was created by heat treatment or some other method, there can be no dispute that in Figures 33-35 it "has" a fixed arc in all of its normal use configurations, including both the expanded and compressed configurations.

Indeed, the very title of the '662 patent illustrates the folly of the PTAB's approach: "Hook for Attaching to a Corporeal Lumen *and Method of Manufacturing*." (A266 (emphasis added).) Although the specification discusses certain methods of manufacturing a hook, those are not claimed in the '662 patent. (*See, e.g.*, A276 at 5:43-6:13.) It was legal error for the PTAB to import those unclaimed limitations—none of which were incorporated into the applicable claim construction—into its analysis of the prior art. *See, e.g., DSW, Inc. v. Shoe Pavilion, Inc.*, 537 F.3d 1342, 1348 (Fed. Cir. 2008) (noting that it is improper to import "limitations from the apparatus and system claims into the method claims").

**2. The Combination of White & Ostrovsky Teaches The Use of the Particular Material that the '662 Patent Identifies As Generating A Permanent Curve**

As discussed in the preceding section, while Ostrovsky does not teach a particular method of manufacturing its fixed-arc hook **206**, it nonetheless teaches that this fixed-arc hook is maintained in all of its configurations during normal use (which is all that is required under the PTAB's claim construction for "permanent curve"). However, if the Federal Circuit were to conclude—contrary to the claim language of the '662 patent and the PTAB's actual claim construction—that the PTAB correctly required that the prior art must teach how to make a permanent curve in order to fall within the scope of the apparatus claims of the '662 patent, the combination of White and Ostrovsky provides such a teaching.

In assessing whether the White-Ostrovsky combination teaches a method for making a permanent curve, the PTAB focused exclusively on one alleged method for how Nitinol can allegedly be heat treated to become permanently curved. (*See* A32.) But that is not the only alleged method of making a permanent curve disclosed in the '662 patent; according to the specification, there are two other methods of obtaining or generating a permanent curve: use of "a ceramic or plastic hook." (A276 at 6:4-5.) During oral argument before the PTAB, LifePort emphasized these alternative methods of creating a permanent curve through use of a particular material. (*See* A233 at ll. 24-25 (LifePort's counsel arguing that the

specification "also tells you that you can use ceramics or plastics" to make a permanent curve).)

Ostrovsky teaches that its endoprosthesis and its "various elements such as struts **202** or loops **210** may be formed from Nitinol, stainless steel or other biocompatible materials." (A295 at 10:9-11.) Consistent with this disclosure, White teaches that other than Nitinol, other biocompatible materials "may also be appropriate for use in the manufacture of the engagement members, *including plastic materials*." (A306 at ll. 34-36 (emphasis added).) While neither the claims nor the claim construction for "permanent curve" requires either heat treatment for Nitinol, or a particular material for making a curve, the combination of White and Ostrovsky discloses the same method of making a permanent curve (*i.e.*, the use of plastic materials) as the '662 patent does. The PTAB's criticism of Medtronic for failing to provide evidence of heat treatment of Nitinol in Ostrovsky is therefore misplaced, and cannot form a basis for rejecting Medtronic's obviousness arguments.

The White-Ostrovsky combination—consisting of two references that were not before the Patent Office during prosecution of the '662 patent—teaches (a) the same type of endoluminal prosthesis as the '662 patent, with (b) the same type of curved hooks as the '662 patent, (c) shown in the same expanded and compressed configurations with the same arc of curvature as the '662 patent, (d) made of the

same material as the device disclosed in the '662 patent. No reasonable fact finder could conclude that the '662 patent claims to a "permanent curve" are anything but obvious in light of these two references. The PTAB's conclusion to the contrary should therefore be reversed.

### **III. THE COURT SHOULD REMAND THIS CASE TO THE PTAB FOR CONSIDERATION OF THE MOTIVATION TO COMBINE THE REFERENCES AT ISSUE**

The PTAB's determinations regarding patentability in the Final Written Decision were based exclusively on its consideration of whether the prior art disclosed a "permanent curve." As discussed above, there was no need for the PTAB to consider in the Final Written Decision whether the combination of White & Ostrovsky disclosed the other elements of claims 1-4, 8-12, and 16 of the '662 patent, or whether the combination of White, Ostrovsky, and Lazarus disclosed the other elements of claims 7 and 15 of the '662 patent (*i.e.*, the use of a barb and the use of an arrowhead configuration, respectively), because the only claim element that LifePort argued was lacking from these combinations was the permanent curve.

The PTAB made no findings as to whether there was any reason to combine White with Ostrovsky, or whether there was any reason to combine White, Ostrovsky, and Lazarus. Because the PTAB erred in its conclusion that the combination of White and Ostrovsky does not teach a "permanent curve," this case

should be remanded to allow the PTAB the first opportunity to make findings regarding the limited issue of whether there is a reason to combine the foregoing references.

### **CONCLUSION AND STATEMENT OF REQUESTED RELIEF**

For reasons set forth above, Medtronic respectfully requests that the PTAB's decision be vacated, and that this case be remanded to the PTAB for limited further proceedings.

/s/ James J. Elacqua

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*Counsel for Appellants*

Dated: September 25, 2015

**ADDENDUM A: FINAL WRITTEN DECISION OF THE PTAB**

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Tel: 571-272-7822

Paper 34  
Entered: April 21, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MEDTRONIC, INC. AND MEDTRONIC VASCULAR, INC.,  
Petitioners,

v.

LIFEPORT SCIENCES LLC,  
Patent Owner.

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Case IPR2014-00288  
Patent 7,147,662

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Before LORA M. GREEN, SCOTT E. KAMHOLZ, and  
ROBERT A. POLLOCK, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

FINAL WRITTEN DECISION  
*35 U.S.C. § 318(a) and 37 C.F.R. § 42.73*

IPR2014-00288  
Patent 7,147,662

## I. INTRODUCTION

### A. *Procedural Posture*

Petitioners, Medtronic, Inc. and Medtronic Vascular, Inc. (collectively, “Petitioners”), filed a corrected Petition (Paper 6, “Pet.”) requesting *inter partes* review of claims 1–16 of U.S. Patent No. 7,147,662 (Ex. 1001, “the ’662 patent”) on multiple grounds. Patent Owner, Lifeport Sciences LLC (“Lifeport”), did not file a preliminary response.

The Board instituted trial for claims 1–5, 7–13, 15, and 16 on certain grounds raised by Petitioners. Decision to Institute 37–38 (Paper 8, “Dec.”). After institution of trial, Lifeport filed a Patent Owner Response (Paper 13, “Resp.”), and Petitioners filed a corresponding Reply (Paper 14, “Reply”). Lifeport did not file a Motion to Amend.

Petitioners rely upon the Declaration (Ex. 1026), supplemental Declaration (Ex. 1034), and deposition testimony of Dr. Gary L. Loomis (Ex. 1035). Lifeport relies on the Declaration of Ellen Golds (Ex. 2001) and excerpts from Dr. Loomis’s deposition (Paper 21). Petitioners filed a Motion to Exclude portions of Dr. Loomis’s testimony (Paper 22 (“Motion to Exclude Evidence”). Lifeport opposes Petitioners’ Motion to Exclude Evidence (Paper 23), and Petitioners filed a Response to Lifeport’s Opposition (Paper 24).

The Board heard oral argument on February 18, 2015. A transcript is entered as Paper 32 (“Tr.”).

The Board has jurisdiction under 35 U.S.C. § 6(c). This final written decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

Petitioners' Motion to Exclude Evidence is dismissed as moot.

The '662 patent relates to a hook for attaching an endoluminal prosthesis, such as a graft or stent, within an artery, vein, or other type of corporeal lumen. Ex. 1001, 1:14–22. The hook is configured for intraluminal delivery and deployment. *Id.* at Abstract. “The hook is integrally formed with [a] framing structure and is preset into an outward bend, but is resiliently flexible so as to form a substantially straight profile when compressed.” *Id.*

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hook 20 bounded on three sides by incisions 40 and forming elongated member 24 and pointed end 26. *Id.* at 4:55–62.

Figure 2 of the '662 patent is reproduced below:

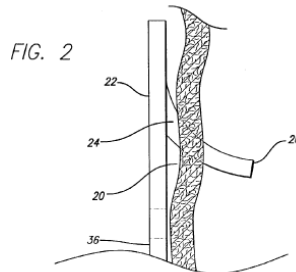


Figure 2 illustrates a side view of frame 22 with a hook 20 in a deployed configuration. *Id.* at 2:47–48. In this embodiment, “force applied downward on the frame 22 causes the hook 20 to embed into the tissue.” *Id.* at 3:19–21. “A preferred configuration is sized to be delivered intraluminally and attach to the inside of a blood vessel.” *Id.* at 3:21–23.

Figure 3 of the '662 patent is reproduced below:

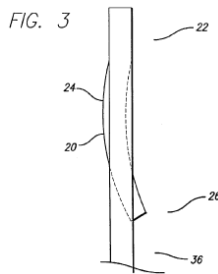
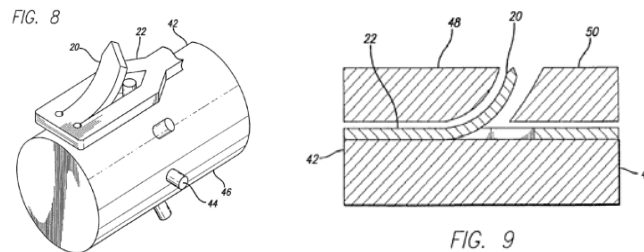


Figure 3 shows a hook 20 in a compressed position that facilitates loading the device into a catheter for delivery. *Id.* at 3:26–37. With respect to Figure 3, “hook 20 is preferably compressed until the hook 20 is within the bounds or circumference of the frame 22.” *Id.* at 3:26–28. In this view, “the combination of the hook 20 and frame 22 forms a nearly flat profile.

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Because the hook 20 has been deformed into a preset bend, the pointed end 26 may still extend a short distance out from the frame 22.” *Id.* at 3:29–33.

Figures 8 and 9 of the ’662 patent are reproduced below:



Figures 8 and 9 illustrate the manufacture of hook 20 on frame 22 using mandrels 42 to force the hook into a predetermined bend. *Id.* at 5:56–67. The bent configuration “can be maintained while the hook 20 is heat set to be permanently predisposed with an outward curve.” *Id.* at 5:60–62. “After bending, the hook 20 may be permanently-deformed into the curved configuration by heat setting the material. For a Nitinol hook 20 and frame 22 combination heating at 550° C. for ten minutes is sufficient.” *Id.* at 6:1–4.

With a permanently deformed hook 20, the hook 20 may still be compressed into alignment with the frame 22 without losing the preset curve. Thus, the hook 20 may be compressed into the frame for intraluminal low profile delivery, and then deployed in the curved configuration by releasing.

*Id.* at 6:7–11.

### C. Illustrative Claim

Claim 1, reproduced below, is illustrative of the claimed subject matter:

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1. A mechanism for securing an endoprosthesis within a corporeal lumen, the mechanism comprising:

a frame element with incisions formed therein, the frame element having a substantially tubular shape and lacking concentrically overlapping structure;

the incisions forming an elongated member having a pointed end, the elongated member being bounded by the frame element; and

the elongated member bent away from said frame element wherein the elongate member has a permanent curve.

*Id.* at 6:22–31.

#### *D. Grounds of Unpatentability*

This proceeding addresses the following instituted grounds of unpatentability:

1. Whether claims 1–3, 5, 9–13, and 16 are anticipated under 35 U.S.C. § 102 by Lefebvre.<sup>1</sup>
2. Whether claims 7, 8, and 15 are obvious under 35 U.S.C. § 103(a) over the combination of Lefebvre and Lazarus.<sup>2</sup>
3. Whether claims 1–4, 8–12, and 16 are obvious under 35 U.S.C. § 103(a) over the combination of White<sup>3</sup> and Ostrovsky.<sup>4</sup>
4. Whether claims 7 and 15 are obvious under 35 U.S.C. § 103(a) over the combination of White, Ostrovsky, and Lazarus.

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<sup>1</sup> US Patent No. 5,108,418, issued Apr. 28, 1992 (Ex. 1003).

<sup>2</sup> US Patent No. 5,562,728, issued Oct. 8, 1996 (Ex. 1006).

<sup>3</sup> PCT International Publication No. WO 00/18322, published Apr. 6, 2000 (Ex. 1004).

<sup>4</sup> US Patent No. 6,447,530 B1, issued Sept. 10, 2002, filed Nov. 25, 1997 (Ex. 1007).

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## II. ANALYSIS

### A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see In re Cuozzo Speed Techs., LLC*, 778 F.3d 1271, 1278–82 (Fed. Cir. Feb. 4, 2015). Under this standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). “Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims. Differences among claims can also be a useful guide in understanding the meaning of particular claim terms.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (citations omitted).

For the purpose of this decision, we focus on the construction of the term “permanent curve.” The ’662 patent does not provide an express definition of this term. Nor does the patent use the precise term “permanent curve” other than in the claims. During examination of the application upon which the ’662 patent issued, however, the Examiner articulated the broadest reasonable construction, in light of the Specification, of “permanent curve” as “a preset curve that . . . maintains a permanent curve regardless of what configuration the device is in.” *See* Ex. 1002, 145 (Examiner’s Reasons for Allowance). Based on that construction, the Examiner allowed the claims. *See id.* at 144–45.

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Citing the testimony of its expert, Gary L. Loomis, Ph.D., Petitioners urged us to adopt the same construction applied by the Examiner. Pet. 9 (citing Ex. 1026 ¶ 60). Dr. Loomis testified that the proffered construction “is supported by the specification and file history and is consistent with that which was applied by the Examiner in his Reasons for Allowance.” Ex. 1026 ¶ 60.

For the purposes of instituting *inter partes* review, we agreed with Petitioners and Petitioners’ expert that the broadest reasonable interpretation consistent with the Specification of a “permanent curve” is “a preset curve that maintains a permanent curve regardless of what configuration the device is in.” Dec. 9 (citing Ex. 1001, 6:1–11). Lifeport and Lifeport’s expert, Ellen Golds, also agreed with that construction. Resp. 7; Ex. 2001 ¶ 27. The parties disagree, however, as to whether, under that construction, a permanent curve encompasses a resilient, flexible member that maintains some degree of curvature—even though the arc of the curve may change due to compressive forces—or whether it more narrowly demands a fixed arc that does not vary during use. *See, e.g.*, Reply 7; Tr. 7:24–8:5, 8:16–25, 23:17–24:3.

Petitioners consider the claims unpatentable according to both interpretations. Tr. 9:1–14. With respect to the broader interpretation, Petitioners’ expert states that the engagement members of Figure 6b of the White reference, “when made of a resilient spring-aided change material such as nitinol, would maintain a permanent curve in both their compressed and expanded positions . . . such spring aided materials, if curved in their uncompressed orientation, would maintain a curve when compressed.” Ex. 1026 ¶ 101; *see also* Pet. 38 (citing Ex. 1026 ¶ 177 (“it is an inherent

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property of the heat aided and spring-aided change materials described in White that the curve would be permanent”).

Lifeport argues that “Dr. Loomis appears to erroneously conflate materials having shape ‘memory’ with materials having a permanent curve.” Resp. 37; *see* Ex. 2001 ¶ 86. In Lifeport’s view, although “a material has ‘memory’ in that it changes shape when compressed and then returns to its prior shape when not compressed,” that is quite different from a “permanent curve,” which is “a preset curve that maintains a permanent curve regardless of what configuration the device is in.” Resp. 37 (citing Ex. 2001 ¶ 86). Lifeport’s expert further emphasizes that engagement members that resiliently return to a memorized shape embody *the opposite* of a permanent curve. Ex. 2001 ¶ 84.

As summarized by Petitioners, Lifeport’s broadest reasonable interpretation of permanent curve thus requires that

the curve of the elongated member/hook/ protrusion must be identical in all configurations of the device, and at all times. Any temporary change to the curvature would mean that it is not permanent, and would fall outside of the scope of the claims. That would exclude a curve that is deformed into a flattened or different curvature during deployment, and that elastically returns to a memorized curvature.

Reply 7 n.5 (internal citations and parenthetical omitted). That definition is consistent with the ordinary meaning of “permanent” as “lasting or continuing for a very long time or forever: not temporary or changing.”<sup>5</sup> *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 n.6 (Fed. Cir.

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<sup>5</sup> MERRIAM-WEBSTER, <http://www.merriam-webster.com/dictionary/permanent> (last accessed Feb. 24, 2015).

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1996) (“[We] may also rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents.”)

The Specification of the ’662 patent references a hook or protrusion as having a “bend” and a “curve.” For example, the Specification teaches that in manufacturing an embodiment of the present invention, “hook 20” may be forced into “a predetermined bend” (Ex. 1001, 5:55–67) and then “permanently-deformed into the curved configuration by heat setting the material” (*id.* at 6:1–3). Independent claims 10 and 16, however, make clear that the terms “bend” and “curve” are not necessarily coextensive. In relevant part, these claims recite (emphasis added):

10. . . . a hook having two sides and a point . . . said hook having **a permanent bend** that forms **a permanent curve**.

16. . . . at least one protrusion . . . having **a resiliently flexible bend** formed therein, wherein the at least one protrusion has **a permanent curve** . . . and the at least one protrusion having a pointed end.

In each case, the claims require a hook or protrusion having both a permanent curve and either a permanent bend (claim 10), or a resiliently flexible bend (claim 16). Thus, with respect to the claimed bend, “resiliently flexible” is an express alternative to “permanent.”

Considering the teachings of the Specification, we conclude that the curve element must be permanent, as recited in the claims, rather than “resiliently flexible.” The Specification teaches that in some embodiments, the hook or protrusion “is resiliently flexible so as to form a substantially straight profile when compressed,” (Ex. 1001, Abstract) but “may be

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permanently-deformed into the curved configuration by heat setting the material” (*id.* at 6:1–4). As emphasized by Lifeport, the Specification teaches that a permanently deformed hook and frame—and, thus, a permanent curve—can be produced by heating Nitinol hook and frame combinations “at 550° for ten minutes.” Resp. 25–26 (citing Ex. 1001, 6:3–4); *see* Ex. 2001 ¶ 77. When thus “permanently deformed,” “hook 20 may still be compressed into alignment with the frame 22 *without losing the preset curve*,” and subsequently “*deployed in the curved configuration by releasing*.” Ex. 1001, 6:7–9 (emphases added).

We further note that the Specification makes clear that the disclosed hooks are incorporated into a variety of devices deployed in the veins of living bodies (*see, e.g.*, Ex. 1001, 3:60–4:8), and subject to various physical forces therein. The ’662 patent, thus, discloses an embodiment having “a plurality of hooks 20 from the same incisions 40,” which “could form hooks 20 which project in opposing directions” and “provide superior resistance to radial and axial loads from the corporeal lumen and blood flow.” Ex. 1001, 5:33–37.

In light of the foregoing, we refine our construction of “permanent curve” to be “a preset curve that maintains a fixed arc throughout normal use regardless of what configuration the device is in.” Insofar as Petitioners, and/or Petitioners’ expert, argue that the challenged claims are unpatentable under multiple constructions of this term, we address only those arguments relevant to this construction below.

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*B. Patentability Analysis*

To prevail in its challenges to claims 1–5, 7–13, 15, and 16, Petitioners must prove unpatentability by a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

In finding a claim anticipated, “[t]he identical invention must be shown in as complete detail as is contained in the . . . claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989). Moreover, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). A finding of inherency “requires that the missing descriptive material is ‘necessarily present,’ not merely probably or possibly present” in the anticipating reference. *Trindec Indus., Inc. v. Top-USA Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002) (quoting *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999)).

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007).

a. *Anticipation of Claims 1–3, 5, 9–13, and 16 by Lefebvre*

Petitioners contend that claims 1–3, 5, 9–13, and 16 are unpatentable as anticipated by Lefebvre. Pet. 11–18. For the reasons set forth below, we

i. *Overview of Lafebvre*

*fig. 1*

As shown in Figure 1, free end 5 of each leg 3 includes two teeth 6, 7. *Id.* at 2:57–59. In a preferred embodiment, the teeth have the form “of two triangles of which the parallel bases, fast with the leg, are spaced apart by a distance of between 2 and 10 mm.” *Id.* at 2:33–36. The “two teeth . . . are

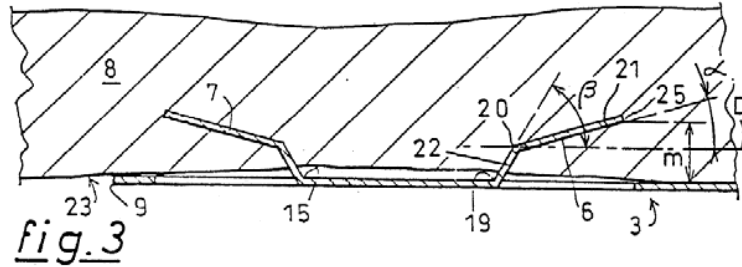
fig. 2

Technical drawing of a mechanical assembly in longitudinal section, labeled fig. 2. The assembly consists of a cylindrical body 5 with a rounded left end 9. Inside the body, there is a central shaft 13 with a conical part 14. A conical part 15 is at the right end of the shaft. A conical part 11 is on the shaft. A conical part 12 is on the shaft. A conical part 17 is on the shaft. A conical part 18 is on the shaft. A conical part 19 is on the shaft. A conical part 10 is on the shaft. A conical part 16 is on the shaft. A conical part 15 is on the shaft. A conical part 14 is on the shaft. A conical part 13 is on the shaft. A conical part 12 is on the shaft. A conical part 11 is on the shaft. A conical part 10 is on the shaft. A conical part 9 is on the shaft. A conical part 8 is on the shaft. A conical part 7 is on the shaft. A conical part 6 is on the shaft. A conical part 5 is on the shaft. A conical part 4 is on the shaft. A conical part 3 is on the shaft. A conical part 2 is on the shaft. A conical part 1 is on the shaft. Dimensions are indicated: 'e' is the distance between the conical part 15 and the conical part 17. 'h' is the distance between the conical part 17 and the conical part 18. 'l' is the length of the conical part 17. 'D' is the diameter of the cylindrical body 5. 'L' is the total length of the assembly.

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Lefebvre Figure 3 is reproduced below:



Lefebvre Figure 3 shows a longitudinal section of the end of a leg 3 positioned against the inner surface 23 of a vein, with teeth 6, 7 penetrating into vein wall 8. *Id.* at 2:47–48; 3:45–48; 4:1–3. Teeth 6, 7 are each bent along an axis of bend 20, which separates the triangular end 25 of the tooth from the trapezoidal base portion 22 having base 19 where the tooth joins leg 3. *Id.* at 3:27–33. Lefebvre Figure 3 shows that two angular measurements,  $\alpha$  and  $\beta$ , converge at bend 20. “The angle  $\alpha$  [is] formed between the triangular end part 21 of the tooth and the direction D’ of the plane of the leg 3,” and “[t]he angle  $\beta$  [is] formed between the trapezoidal part 22 of the tooth and the direction D’ of the plane of the leg 3.” *Id.* at 3:34–41.

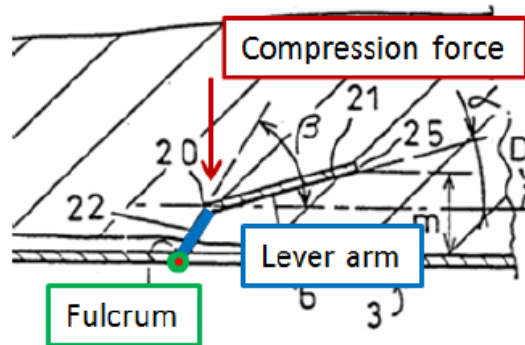
## ii. Analysis

Petitioners contend that Lefebvre’s device has a permanent curve under Lifeport’s construction of the term which, as explained above, is reasonably consistent with our construction (i.e., a preset curve that maintains a fixed arc throughout normal use regardless of what configuration the device is in). *See* Reply 7. In particular, Petitioners rely on Dr. Loomis in asserting that “the geometry disclosed in Lefebvre allows a

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tooth made of elastic material to maintain the same curvature at bend 20 despite conformational changes,” and “[a]s the device is inserted into the catheter bend 20 remains unchanged when the tooth is compressed within the frame.” *Id.* (citing Ex. 1034 ¶¶ 5–9.)

Dr. Loomis models the geometry of tooth 6 in Lefebvre Figure 6 when a catheter sheath or “other force”<sup>6</sup> compresses the Lefebvre device. Ex. 1034 ¶¶ 5–9. Dr. Loomis’s first illustration of a modified version of Lefebvre Figure 6 is reproduced below.



According to Dr. Loomis, this figure shows:

When the catheter sheath or other force compresses the device, the geometry of the tooth directs the point of contact to bend 20, where the compression force will act. The compression force is transferred along trapezoidal part 22, which acts as a lever arm with a fulcrum where trapezoidal part 22 contacts the base 19.

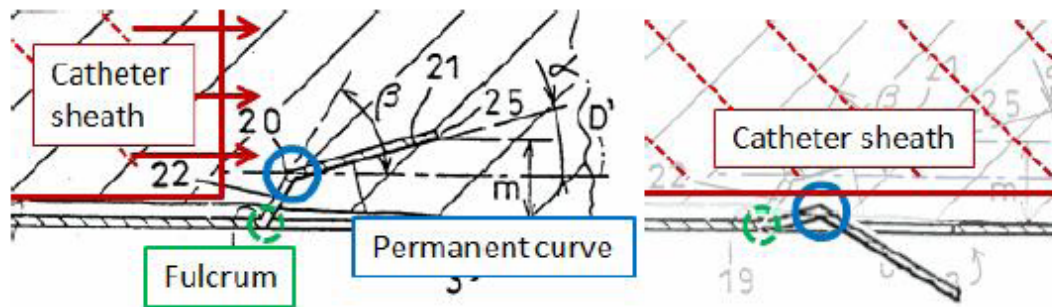
Ex.1034 ¶ 6.

Dr. Loomis’s second and third illustrations are adapted from Lefebvre Figure 6 and are reproduced below.

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<sup>6</sup> Although Dr. Loomis indicates that some “other force” may compresses the Lefebvre device (Ex. 1034 ¶ 6), the only force addressed in his opinion comes from the application of a catheter sheath.

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According to the adapted illustrations, as the catheter sheath advances from left to right, tooth 6 compresses but bend 20 remains unchanged.<sup>7</sup> *See id.* ¶¶ 7–8. In this model, “the point of contact remains at bend 20, there is no force acting on any portion of end part 21.” *Id.* ¶ 8. “Accordingly,” Dr. Loomis explains, “there is no force that will change the angle made at bend 20, which remains constant through the conformational change. In this way, bend 20 is a permanent curve as claimed in the ’662 patent.”<sup>8</sup> *Id.* In sum, Dr. Loomis testifies that as the catheter sheath covers the Lefebvre device, “there will be portions of the curve formed in place of bend 20 that do not experience any force from the catheter. Those portions will remain unchanged and maintain the same curve in either the compressed or expanded configurations.” *Id.* ¶ 10.

<sup>7</sup> Dr. Loomis testified that he could have just as easily based his analysis on tooth 7, in which case the catheter sheath would be shown as moving from right to left. Tr. 57:1–10.

<sup>8</sup> Dr. Loomis further states that the ’662 patent similarly discloses “elastic deformation at the base of the tooth . . . where the base of the engagement member acts as a fulcrum to allow the engagement member to be compressed within the frame.” *Id.* ¶ 9 (referencing Ex. 1001, Figs. 2 and 3, 3:26–28).

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Lifeport asserts that Petitioners fail to establish by a preponderance of evidence that Lefebvre teaches a permanent curve. Resp. 22–26. Lifeport’s expert argues that nothing in Lefebvre indicates that the teeth have a permanent curve. *Id.* (citing Ex. 2001 ¶¶ 75–78); *see* Ex. 2001 ¶47. To the contrary, because the teeth are cut from leg 3, which is expressly described as elastic, a person of ordinary skill in the art would conclude that teeth do not have a permanent curve. *See id.* ¶ 47.

Lifeport has the more persuasive position. First, we note that endoprostheses such as those disclosed in the ’662 patent are deployed and function in a living body (*see, e.g.*, Ex. 1001, 3:60–4:8). Accordingly, our construction of permanent curve as a preset curve that maintains a fixed arc *throughout normal use* regardless of the configuration of the device, is not limited to sheathed and unsheathed configurations taken in isolation.

Thus, whereas Dr. Loomis’s analysis of Lefebvre focuses on the force applied by a catheter sheath impinging on a single tooth of the Lefebvre device, “throughout normal use” more broadly encompasses the deployed configuration of Lefebvre Figure 3 in which teeth 6, 7 penetrate into the vein wall “one in the direction of flow of the blood and the other in the opposite direction.” *See* Ex. 1003, 1:64–66. Dr. Loomis addressed the compressive effects during the application of a catheter sheath. We find no evidence that Dr. Loomis addressed compressive, hemodynamic, or other forces on the Lefebvre teeth when the device is deployed and functioning in normal use.<sup>9</sup>

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<sup>9</sup> Although an analysis of the forces applied to the Lefebvre device when it is deployed in a vein is among the issues raised in Medtronic’s Motion to Exclude Evidence, we need not resort to Dr. Loomis’s contested testimony as the omission is self-evident. We also are not persuaded by Medtronic’s assertion that Figure 3 and column 3, lines 34–42, of Lefebvre demonstrate

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The evidence of record is, therefore, insufficient to demonstrate that Lefebvre maintains a permanent curve as properly construed.

Second, with respect to the configurations of Lefebvre that Dr. Loomis does address, we find his analysis speculative and accord it little weight. It is within our discretion to assign the appropriate weight to be accorded to evidence. *See Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985) (under the Federal Rules of Evidence, which are applicable here,<sup>10</sup> “[o]pinion testimony rendered by experts must be given consideration, and while not controlling, generally is entitled to some weight. Lack of factual support for expert opinion going to factual determinations, however, may render the testimony of little probative value in a validity determination.”) (citations omitted); *see also In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1368 (Fed. Cir. 2004) (“[T]he Board is entitled to weigh the declarations . . . and conclude that the lack of factual corroboration warrants discounting the opinions expressed in the declarations.”).

In weighing Petitioners’ expert testimony, we take into account the lack of evidence that Dr. Loomis (1) considered the physical dimensions of the Lefebvre components, such as the distance between teeth, and the

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that the angles of teeth 6, 7 do not change when impaled in the vein. Tr. 12:1–13:18. The specifically recited angles for  $\alpha$  ( $15^\circ$ ) and  $\beta$  ( $60^\circ$ ) of Lefebvre Figure 3 (“the example” of the referenced passage) refer to the device as shown deployed in the vein. On the record before us, we agree with Lifeport that the cited passage is “not saying that it maintains that shape in all configurations of the device.” *Id.* at 25:10–17.

<sup>10</sup> *See* 37 C.F.R. § 42.62 (“the Federal Rules of Evidence shall apply to” an *inter partes* review, except for exclusions not applicable here).

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clearance between a catheter sheath and elements of the Lefebvre device—including the second, opposing tooth<sup>11</sup> (*see* Ex. 1035, 21:7–15, 29:2–10; Tr. 48:19–20:4); (2) took into account material properties of the metal used to form the Lefebvre legs and teeth, such as the modulus of elasticity<sup>12</sup> (Ex. 1035, 15:9–24 (Lefebvre “[d]oes not disclose a specific elastic modulus of the metal used.”); *see also id.* at 27:14–21 (“For the sake of my analysis, I didn’t make any assumptions as to whether [the tooth and leg] were the same material or . . . different materials.”)); or (3) employed any computer modeling, physical models, or mockup of any embodiment disclosed in Lefebvre (*id.* at 16:24–17:6; 17:7–18:6; *see* Tr. 13:19–14:2). Those factors point to a lack of rigor and reliability in Dr. Loomis’s analysis.

Our concerns are heightened by Dr. Loomis’s apparent lack of expertise in the relevant field. Although Dr. Loomis testified that he took “seminars on mechanical behaviors of metals as used in the biomedical device industry” (*id.* at 10:1–6), and as “the director [of] mechanical analysis of materials used in medical devices” (*id.* at 10:19–20), oversaw the “stress/strain analysis testing, radio compression analysis done on

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<sup>11</sup> At best, Dr. Loomis testified that the opposing teeth “would have to be compressed or else they would embed in the catheter,” but provided no indication how that would be accomplished according to his model. *See* Tr. 57:11–58:3.

<sup>12</sup> According to Dr. Loomis, modulus of elasticity is “a way of describing the force required to stretch a material. The higher the modulus, the more force is required to stretch [or deform] the material.” Ex. 1035, 12:18–25; *see also*, DICTIONARY.COM, <http://dictionary.reference.com/browse/modulus+of+elasticity> (last accessed 26 February 2015) (Defining modulus of elasticity as “any of several coefficients of elasticity of a body, expressing the ratio between a stress or force per unit area that acts to deform the body and the corresponding fractional deformation caused by the stress.”)

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instruments such as Instron” (*id.* at 10:13–20), Dr. Loomis is, by training, an organic chemist<sup>13</sup> with extensive experience in polymers, most notably, biopolymers. *See* Ex. 1026 ¶ 3; Ex. 1027. Dr. Loomis’s credentials in these areas are notable, but they are not well matched to the mechanical and structural issues of the present matter. By contrast, we find that Lifeport’s expert, Ms. Golds, has substantial and highly relevant experience in the design, development, manufacture, and testing of vascular implants, including vena cava filters and self-expanding Nitinol stents. *See* Ex. 2001, ¶¶ 3–13, App.; *see also* Reply at 10 (“[P]ersons of ordinary skill routinely worked simultaneously on both stent and filter design, as Ms. Golds herself did at AlvaMed.”).

Third, noting that the ’662 patent teaches that “hook 20 may be permanently-deformed into the curved configuration by heat setting the material” (Ex. 1001, 6:1–4), we find no corresponding disclosure in Lefebvre. In accord with this finding, we credit the testimony of Lifeport’s expert, Ms. Golds, that there is “no teaching in Lefebvre of ‘heating [nitinol] at 550° for ten minutes,’ or any other conditions which would cause the curve in the tooth to be ‘permanent’ such that it maintains a permanent curve regardless of what configuration the device is in.” Ex. 2001 ¶ 77.

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<sup>13</sup> Dr. Loomis contends that a person of ordinary skill in the art would, *inter alia*, possess “a degree in biomedical, mechanical, or chemical engineering or material science.” Ex. 1026 ¶ 44. Dr. Loomis has undergraduate training in electrical engineering (Ex. 1035, 9:3–21), a master’s degree in chemistry and a Ph.D. in Organic Chemistry (Biochemistry minor) (Ex. 1027, 3), and, thus, does not possess the educational background required by his own definition. Ms. Golds, by contrast, does meet Dr. Loomis’s educational requirement, holding a bachelor’s degree in Biomedical Engineering with a specialty in Mechanical Engineering. Ex. 2001, 1–2, App.

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“Certainly, it cannot be said that teeth 7 necessarily have a permanent curve.” *Id.* ¶ 75.

For the reasons discussed above, we conclude that Petitioners have not proven by a preponderance of the evidence that Lefebvre renders claims 1–5, 7–13, 15, and 16 unpatentable under 35 U.S.C. § 102.

b. *Obviousness of Claims 7, 8, and 15 in view of Lefebvre and Lazarus*

Petitioners contend that claims 7, 8, and 15 are unpatentable as obvious in view of Lefebvre and Lazarus. Pet. 19–23; Reply 9–10, 14–15; *see* Ex 1026, 40–43. Claims 7 and 8, depending from independent claim 1, and claim 15, depending from independent claim 10, recite a pointed end of the elongated member having at least one barb (claim 7), that the pointed end is “sharpened” (claim 8), and that the point is formed in an “arrowhead configuration” (claim 15). In asserting obviousness, Petitioners rely on Lazarus solely for the use of specially configured pointed ends. At pages 21–22 of the Petition, for example, Petitioners state:

Lazarus specifically teaches that by modifying hooks like those of Lefebvre to make them sharper, or to configure them as barbs or arrowheads, *more secure anchoring* of the device can be achieved. . . . Thus, a person of skill in the art dealing with the problem of intraluminal device migration would have been motivated to combine the teaching of Lazarus with that of Lefebvre to achieve even stronger anchoring of the device to the lumen wall.

For the reasons discussed above, we find that Lefebvre fails to disclose or suggest the “permanent curve” set forth in independent claims 1 and 10, from which claims 7, 8, and 15 depend. As there is no assertion of

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record that the missing element is provided in Lazarus, we conclude that Petitioners have not proven by a preponderance of the evidence that the combination of Lefebvre and Lazarus renders claims 7, 8, and 15 unpatentable under 35 U.S.C. § 103(a).

*c. Obviousness of Claims 1–4, 8–12, and 16 in view of White and Ostrovsky*

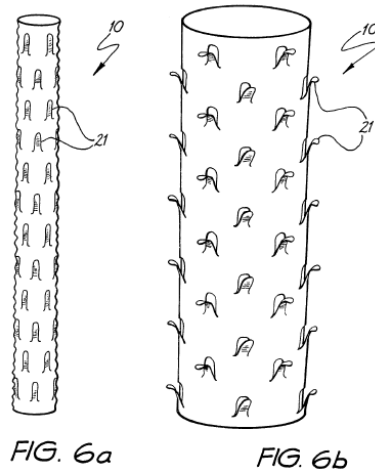
Petitioners contend that claims 1–4, 8–12, and 16 are unpatentable as obvious in view of White and Ostrovsky. Pet. 46–56; Reply 11–14; *see* Ex. 1026, 32–35, 70–81; Ex. 1034, 5–8. For the reasons set forth below, we find that Petitioners have failed to establish that the combination of White and Ostrovsky teaches or suggests a “permanent curve” and, thus, has not proven by a preponderance of evidence that the asserted combination renders claims 1–4, 8–12, and 16 obvious.

*i. Overview of White*

White describes an intraluminal device for treating aneurysms and other vascular diseases. Ex. 1004, Abstract. White’s device has “a tubular body with two ends” that can expand “from a radially compressed state to a radially expanded state.” *Id.* at 2:8–11. White’s device includes “engagement members,” preferably formed of Nitinol, stainless steel or other “memory” alloy. *Id.* at 8:31–34. Each engagement member is defined by “a small incision in the wall of the device” (*id.* at 17:1–3), is “integral with a wall of the device body” (*id.* at 8:20–23) and “act[s] as an attachment, hook, or anchor to prevent the device from moving longitudinally within the vessel” (*id.* at 7:34–8:2).

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White Figures 6a and 6b are reproduced below:



White Figure 6a illustrates device 10 in a compressed state; Figure 6b illustrates the same device in an expanded condition. *Id.* at 14:22–28. The device 10 shown in Figures 6a and 6b includes engagement members 21 in two configurations. *Id.* at 16:34–17:3. White describes that, in the compressed state, the angular relationships of the engagement members to the wall of the device body “may be either flat, running along or forming a part of the wall of the device body or, alternatively, the engagement members may project inwardly, within the lumen of the device body.” *Id.* at 9:28–33. According to White, that allows maintaining “the smallest possible diameter along the length of the device body . . . when the device body is in a radially compressed state.” *Id.* at 9:33–36. In the expanded state, the engagement members are “splayed out from the wall of the device body into [a different] . . . angular relationship” with the wall of the device body. *Id.* at 14:25–28. White also indicates that the once the device has been positioned in the selected vessel, the engagement members may change from the compressed state to the expanded state “without specific assistance from the surgeon.” *Id.* at 10:3–7.

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One mechanism by which the White device may change from a compressed state to an expanded state is by “a spring-aided change,” which occurs when “the material comprising the engagement members has a ‘memory’ of [the angular relationship of the engagement members in the expanded position] . . . such that the engagement members may ‘spring’ into that position upon release from the catheter.” *Id.* at 10:18–23. In that embodiment, the device is manufactured from alloys “which have the capacity to ‘memorise’ their manufactured shape, such that the device, according to this invention, will have a continuous tendency to return to its original shape following any events which cause it to be temporarily deformed.” *Id.* at 7:6–11.

In another embodiment, the change from a radially compressed state (Figure 6a) to a radially expanded state (Figure 6b) is mediated by thermal expansion. *Id.* at 16:34–17:15. In that embodiment, engagement members 21 are cut from a Nitinol frame and heat treated such that the engagement members “have the capacity, following a rise in temperature, to splay out from a wall of the device.” *Id.* at 17:8–11.

ii. *Analysis*

In asserting that White teaches a permanent curve, Petitioners rely on Figures 6a, 6b, and the following passage from the reference:

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the device body and the engagement members will be such that when the device body is in a radially compressed state, the respective first angular relationships of the engagement members may be either flat, running along or forming a part of the wall of the device body or, alternatively, the engagement members may project inwardly, within the lumen of the device body.

Pet. 50 (citing Ex. 1004, 9:29–33, Figs. 6a, 6b); *see id.* at 55. Petitioners’ expert, Dr. Loomis, explains that White discloses “four ways in which an engagement member can change its angular relationship to the device once it is introduced to the vessel,” including heat-aided change in response to body temperature and spring aided change in which the member returns to a memorized shape upon the release of a compressive force. Ex. 1026 ¶ 99. The angular relationship of the engagement members to the body wall may be flat “or the engagement members might even project inwardly so the device maintains the smallest profile possible.” *Id.* ¶ 100 (citing Ex. 1004, 9:27–10:2.)

Petitioners argue that White’s spring expansion embodiment “allows for temporary deformation of the device into a compressed state without altering the curvature of any protrusion.” Reply 11. We discern no evidence for this assertion other than Dr. Loomis’s statement that, in the White’s spring-aided device, “the engagement members that project outwardly when expanded can ‘project inwardly, within the lumen of the device’ when compressed.” Ex. 1034 ¶ 22 (quoting Ex. 1004, 9:27–33). We do not find Dr. Loomis’s assertion persuasive. *See Am. Acad. of Sci. Tech Ctr.*, 367 F.3d at 1368 (“[T]he Board is entitled to weigh the declarations [offered in the course of prosecution] and conclude that the lack of factual corroboration warrants discounting the opinions expressed in the declarations.”).

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Dr. Loomis further asserts that expansion of the White device “is analogous to the engagement member disclosed in the ’662 patent in Figures 2 and 3, where the engagement member projects inwards from the frame.” Ex. 1034 ¶ 22; *see* Reply 11. We are not persuaded that Dr. Loomis’s comparison to the embodiments shown in Figures 2 and 3 of the ’662 patent is sufficient, as nothing in the Specification requires that those embodiments comprise a permanent curve. To the contrary, the permissive language of the Specification that hook 20 “*may* be permanently-deformed into the curved configuration by heat setting the material” (Ex. 1001, 5:60–62 (emphasis added)), indicates that those embodiments may fall outside the claims ultimately issued. *See also id.* at 6:7–9 (“With a permanently deformed hook 20, the hook 20 may still be compressed into alignment with the frame 22 without losing the preset curve.”).

Dr. Loomis further states that

one skilled in the art would have recognized that the engagement members of Figure 6b, when made of a resilient spring-aided change material such as nitinol, would maintain a permanent curve in both their compressed and expanded positions. Further, it is my opinion that one skilled in the art would have recognized that such spring aided materials, if curved in their uncompressed orientation, would maintain a curve when compressed.

Ex. 1026 ¶ 101; *see also* Reply 11.

We do not discern, nor does Dr. Loomis adequately explain, how the angular relationship of White’s engagement members, whether in an expanded, flat, or inwardly-projection configuration, comports with our construction of permanent curve. At best, Dr. Loomis identifies changes in the shape of White’s engagement members in response to temperature or

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compressive forces. On their face, such changes are incompatible with a permanent curve that is a preset curve that maintains a fixed arc throughout normal use regardless of what configuration the device is in. Dr. Loomis has not convinced us of a contrary interpretation of the White reference. Accordingly, we credit Ms. Gold's testimony that "[n]othing in the disclosure of White indicates that the engagement members 21 have a permanent curve." Ex. 2001 ¶ 59.

iii. *Overview of Ostrovsky*

Ostrovsky describes a "recoverable thrombosis filter that can be implanted and securely positioned within a vein at a desired location, and can be recovered through an endovenous route." Ex. 1007, Abstract. "The various components of the filter can be constructed of a class of elastic materials including nitinol, stainless steel, platinum, tungsten, titanium, and chromium alloys." *Id.* at 10:65–11:1. "The selection of materials will also determine the flexibility and resiliency of the various members." *Id.* at 10:63–65.

Ostrovsky's filter comprises "a generally conical structure" having "shaped ends for engaging an inner lumen wall" (*id.* at 3:7–11), as can be seen in Ostrovsky Figure 2, reproduced below:

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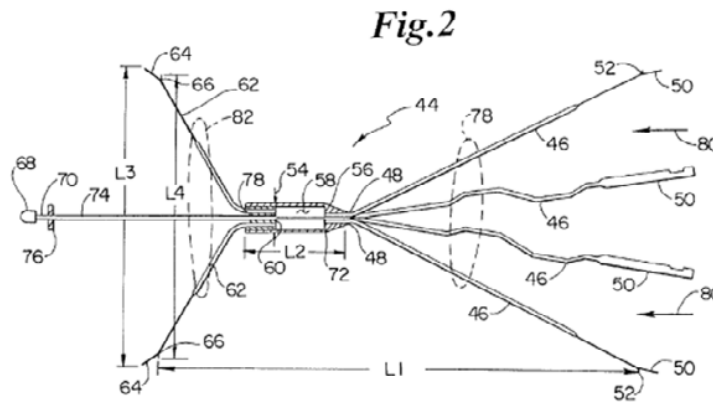
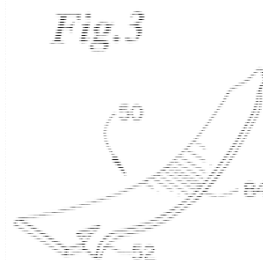


Figure 2 illustrates Ostrovsky's filter 44. *Id.* at 3:66–67. At one end of filter 44, flexible anchoring struts 62 “project outwardly to wall engaging surfaces 64. Projections 66 function to position and hold filter 44 in position when engaged to an inner vein wall.” *Id.* at 5:40–43. At the opposite end, filter 44 has “shaped filtering elements 46, each having a mounting end 48 and a wall engaging end 50.” *Id.* at 5:31–33. Wall engaging end 50 of element 46 has projections 52 to engage a vein wall. *Id.* at 5:31–34, 6:2–3. Ostrovsky discloses that element 46 may comprise a flat wire having, for example, a thickness of 0.0006 inch and a width of 0.026 inch, and that differences in relative thickness relative to width will affect the flexibility of the element. *Id.* at 6:10–14.

Ostrovsky Figure 3 is reproduced below:



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Figure 3 illustrates a wall engaging end 50 of element 48. *Id.* at 4:1–2. Wall engaging end 50, shown in Figure 3, has “a generally curved structure and is flattened to a desired dimension such that the under surface 84 will slidably engage an associated vein wall.” *Id.* at 5:65–6:1. “The thickness [of engaging end 50] is selected for the desired flexibility.” *Id.* at 6:1–2. Ostrovsky discloses that “[a] similar configuration is utilized for the anchoring elements,” such as anchoring struts 62 shown in Figure 2 (previously presented). *Id.* at 6:3–4.

Figures 33 and 34 show an embodiment of Ostrovsky’s filter in two stages of being extracted from the vascular system. *Id.* at 4:64–67.

Ostrovsky Figure 33 is reproduced below:

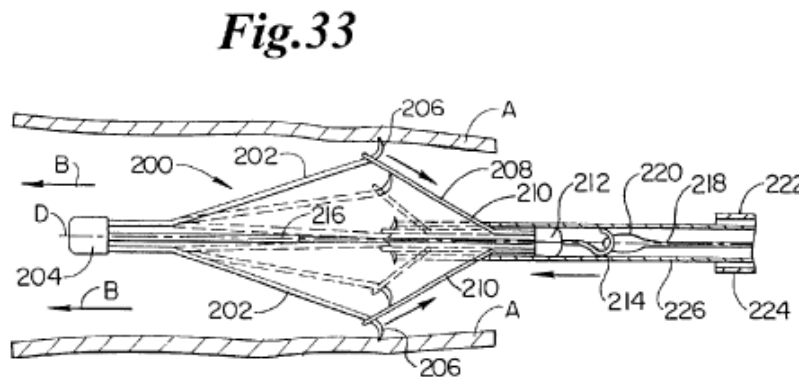


Figure 33 illustrates an early stage of retrieving a filter from blood vessel A. *Id.* at 4:64–65. Ostrovsky’s filter includes a flexible anchoring strut 202 with end 206 that is “sharpened and barbed to engage with the wall of vessel A,” as shown in Figure 33. *Id.* at 9:65–67. Blood flow is in the direction of arrows B. *See id.* at 9:58–62.

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Ostrovsky Figure 34 is reproduced below:

**Fig.34**

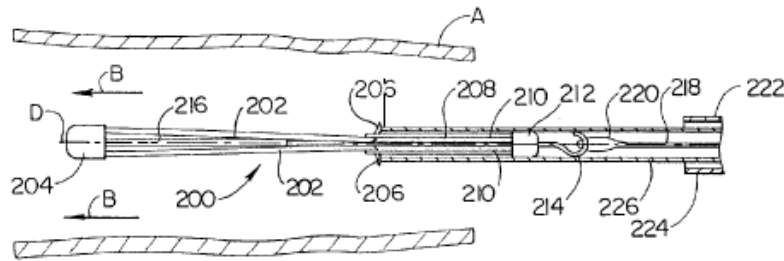


Figure 34 illustrates a later stage of retrieving a filter from a vascular system. *Id.* at 5:1–2. As shown in Figure 34, element 206, the hook-like end of strut 202 has been disengaged from the wall of vessel A, brought to a position adjacent axis D of filter 200, and into contact with inner tube 226. *Id.* at 10:34–43.

iv. *Analysis*

Petitioners contend that Ostrovsky “teaches the use of permanently curved, pointed hooks on a recoverable thrombosis filter for intraluminal implantation” (Pet. 26 (citing Ex. 1007, Abstract, Figs. 3 and 24)); that Ostrovsky Figure 3 “discloses the elongated member (52) bent away from the frame element (50) wherein the elongated member (52) has a permanent curve” (*id.* at 50); and that Ostrovsky Figures 33 and 34 disclose hook-like elements 206 to anchor the device to the lumen wall firmly, wherein these elements “maintain a curve in both their compressed and expanded configurations” (*id.* at 27; *see also* Reply 11 (asserting that hooks 206 “maintain an identical curve in each state”)).

Dr. Loomis asserts that Ostrovsky “discloses a curve hook with a curve and materials that would maintain a permanent curve.” Ex. 1026 ¶ 136; *see id.* ¶ 109 (noting that “outward projection (52) has a permanent

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curve”). Although Ostrovsky discloses the use of “*elastic* materials including nitinol, stainless steel, platinum, tungsten, titanium, and chromium alloys” (Ex. 1007, 10:65–11:1 (emphasis added)), Dr. Loomis fails to explain how the reference teaches the generation of a *permanent* curve, as is taught, for example, at column 6, lines 1–4, of the ’662 patent (heating a Nitinol hook and frame combination “at 550° C. for ten minutes”).

We also take note of Dr. Loomis’s failure to address the forces acting on any part of an Ostrovsky device alleged to teach or disclose a permanent curve. For example, as shown in Ostrovsky Figure 33, reproduced above, hook-like elements 206 are anchored in the wall of blood vessel A as blood flows through the filter in the direction of arrows B. Figures 33 and 34 further show that in normal use, the filter may be removed from the vessel in the opposite direction of blood flow. We find no evidence that Dr. Loomis addressed these or any other forces acting upon the hook-like elements 206 when the Ostrovsky device is deployed in normal use. Accordingly, we find the evidence of record insufficient to demonstrate that Ostrovsky maintains a permanent curve as defined herein.

In light of the above, we conclude that Petitioners have not proven by a preponderance of the evidence that the combination of White and Ostrovsky renders claims 1–4, 8–12, and 16 unpatentable under 35 U.S.C. § 103(a).

d. *Obviousness of Claims 7 and 15 in view of White, Ostrovsky, and Lazarus*

Petitioners contend that claims 7 and 15 are unpatentable as obvious in view of White, Ostrovsky, and Lazarus. As discussed above, Petitioners have not shown that any of these references teach or suggest a permanent

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curve as construed herein. We, therefore, conclude that Petitioners have not proven by a preponderance of the evidence that the combination of White, Ostrovsky, and Lazarus renders claims 7 and 15 unpatentable under 35 U.S.C. § 103(a).

### III. MOTION TO EXCLUDE EVIDENCE

Petitioners move to exclude portions of the deposition transcript of Dr. Gary L. Loomis as exceeding the scope of rebuttal evidence. Paper 22.

We dismiss Petitioners' Motion as moot because we do not rely on any of the objected-to testimony in our final decision.

### IV. CONCLUSION

Petitioners have not proven, by a preponderance of evidence, that any of claims 1–5, 7–13, 15, and 16 are unpatentable over the cited prior art.

### V. ORDER

After due consideration of the record before us, it is

ORDERED that claims 1–5, 7–13, 15 and 16 of U.S. Patent No. 7,147,662 are not determined to be unpatentable;

FURTHER ORDERED that Medtronic's Motion to Exclude Evidence is dismissed as moot; and

FURTHER ORDERED that because this is a final decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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**ADDENDUM B: U.S. PATENT NO. 7,147,662**



US007147662B1

(12) **United States Patent**  
**Pollock et al.**

(10) **Patent No.:** **US 7,147,662 B1**  
(45) **Date of Patent:** **\*Dec. 12, 2006**

(54) **HOOK FOR ATTACHING TO A CORPOREAL LUMEN AND METHOD OF MANUFACTURING**

(75) Inventors: **David T. Pollock**, Burlingame, CA (US); **Peter Johansson**, Campbell, CA (US)

(73) Assignee: **Endovascular Technologies, Inc.**, Santa Clara, CA (US)

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 465 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **10/326,719**

(22) Filed: **Dec. 19, 2002**

#### Related U.S. Application Data

(63) Continuation of application No. 09/547,822, filed on Apr. 11, 2000, now Pat. No. 6,517,573.

(51) **Int. Cl.**  
**A61F 2/06** (2006.01)

(52) **U.S. Cl.** ..... **623/1.36**; 623/1.15; 623/1.13

(58) **Field of Classification Search** ..... 606/200; 623/1.36, 1.13, 1.15  
See application file for complete search history.

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*Primary Examiner*—Anh Tuan T. Nguyen

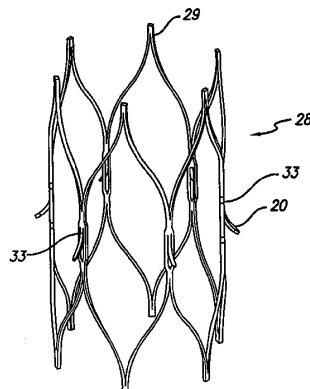
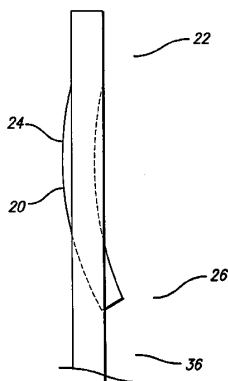
*Assistant Examiner*—E Houston

(74) *Attorney, Agent, or Firm*—Fulwider Patton LLP

(57) **ABSTRACT**

An improved hook provides for the attaching of endoluminal prosthesis within corporeal lumens. The hook is integrally formed with framing structure and is preset into an outward bend, but is resiliently flexible so as to form a substantially straight profile when compressed. The hook is capable of impinging upon the corporeal lumen and thereby securing the prosthesis. The hook may be configured for intraluminal delivery and deployment. A novel method of manufacturing said hook is also provided.

**16 Claims, 6 Drawing Sheets**



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FIG. 1

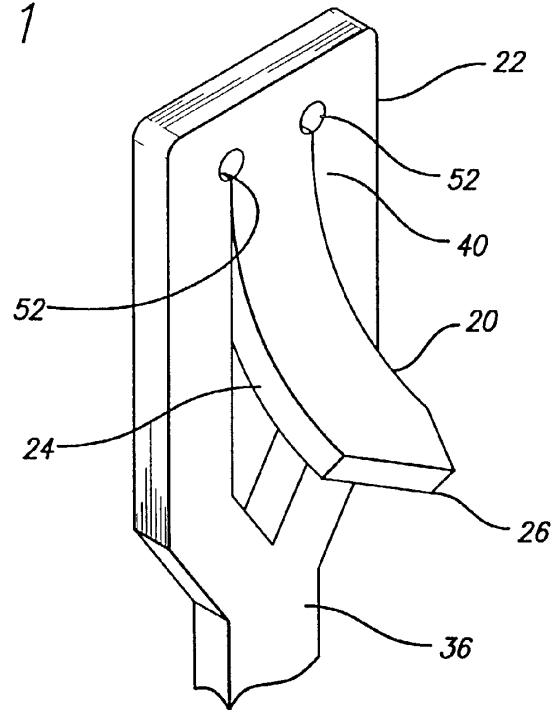
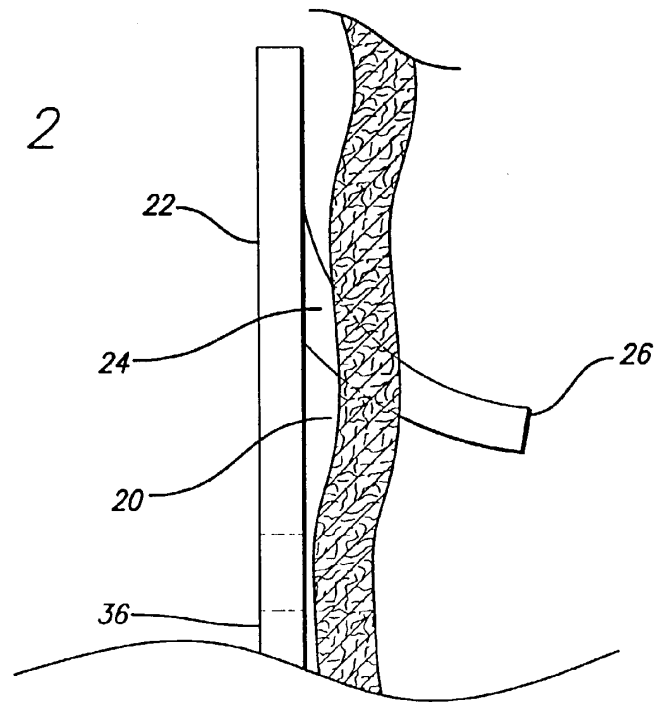


FIG. 2

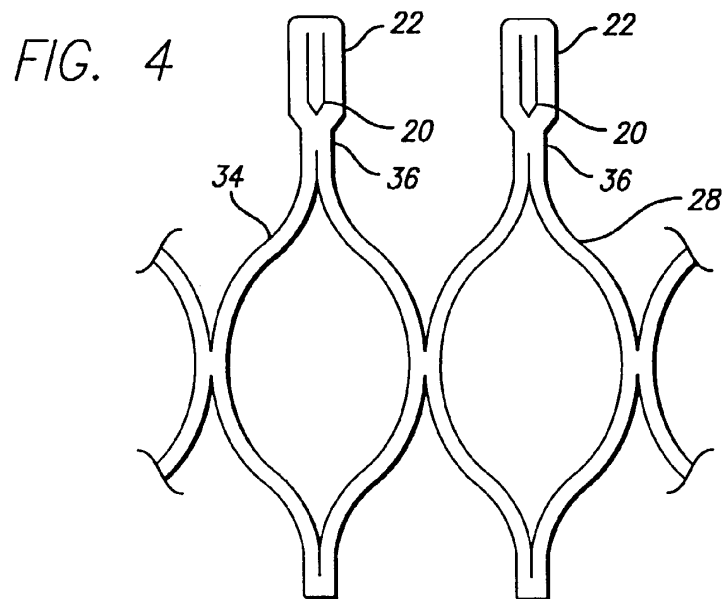
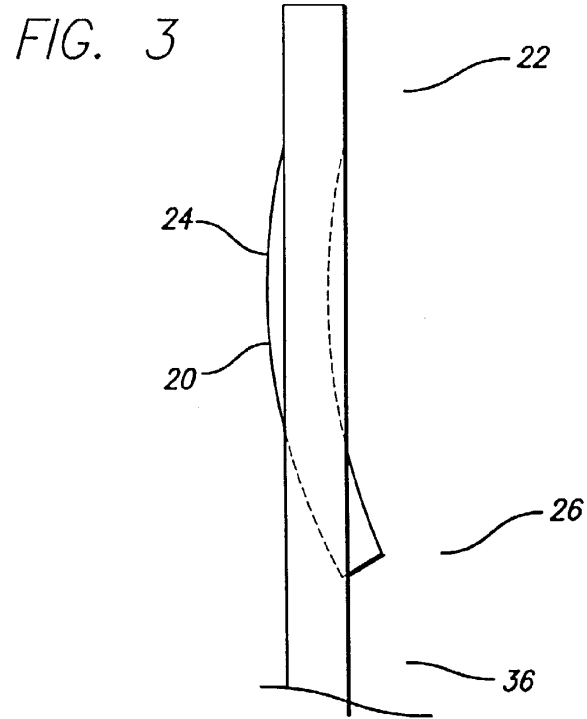


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FIG. 5

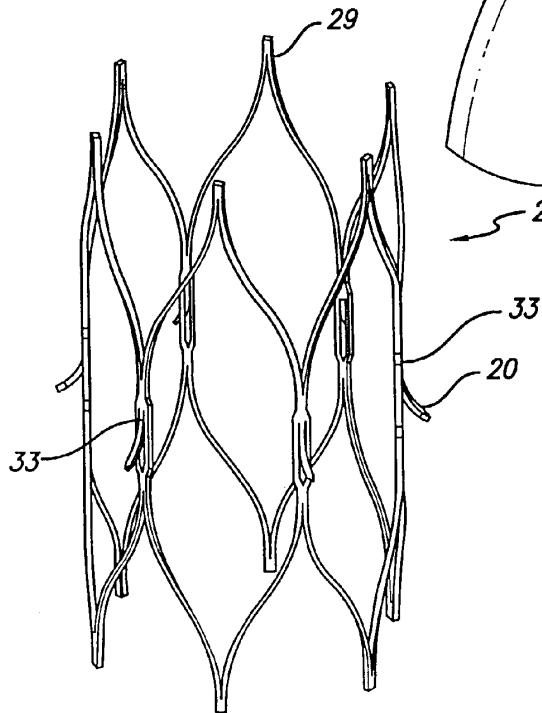
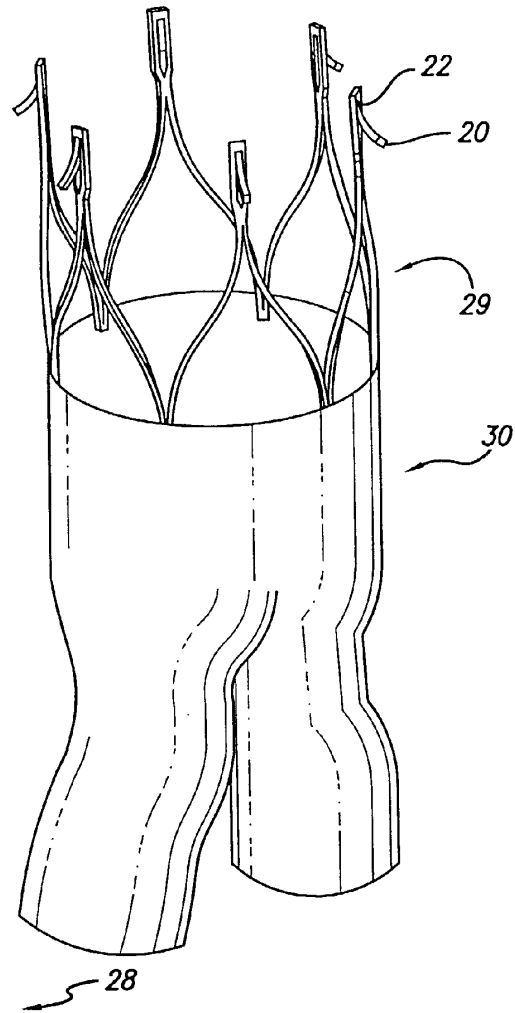


FIG. 6

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FIG. 7A

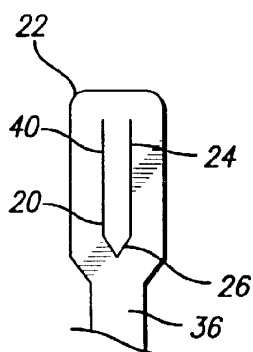


FIG. 7B

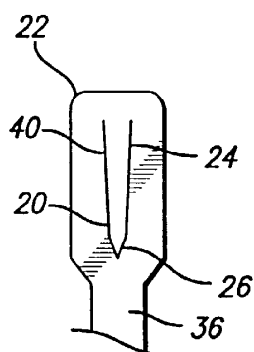


FIG. 7C

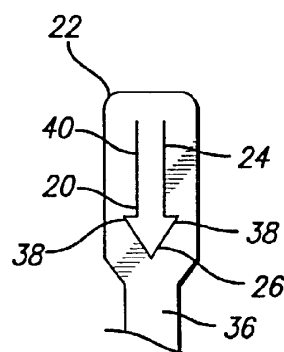


FIG. 7D

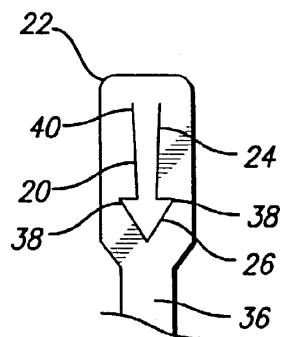
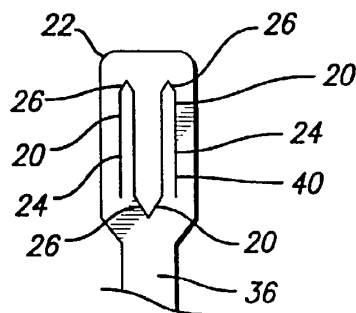


FIG. 7E

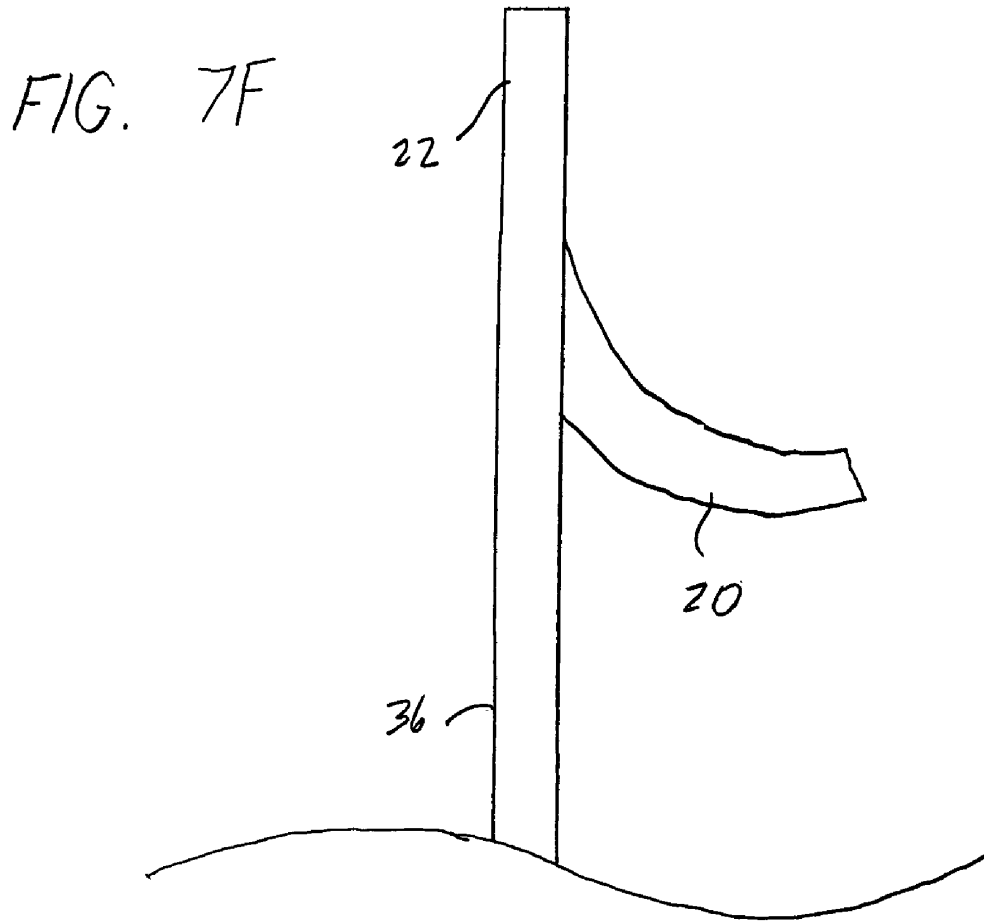


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FIG. 8

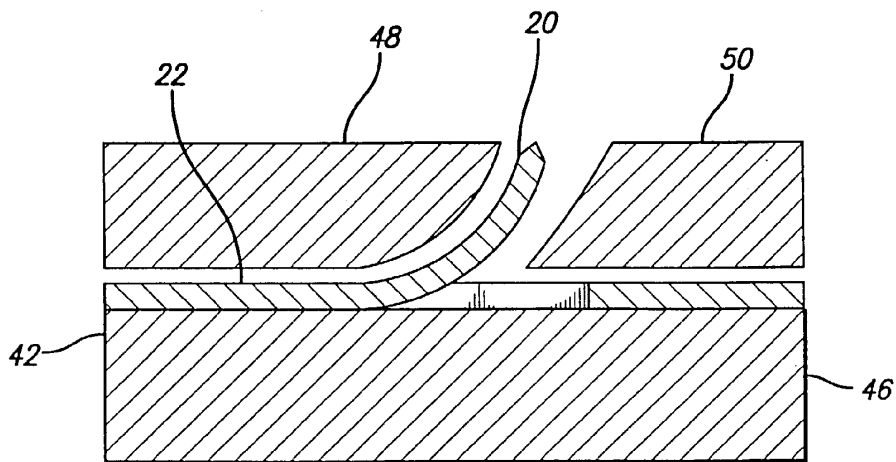
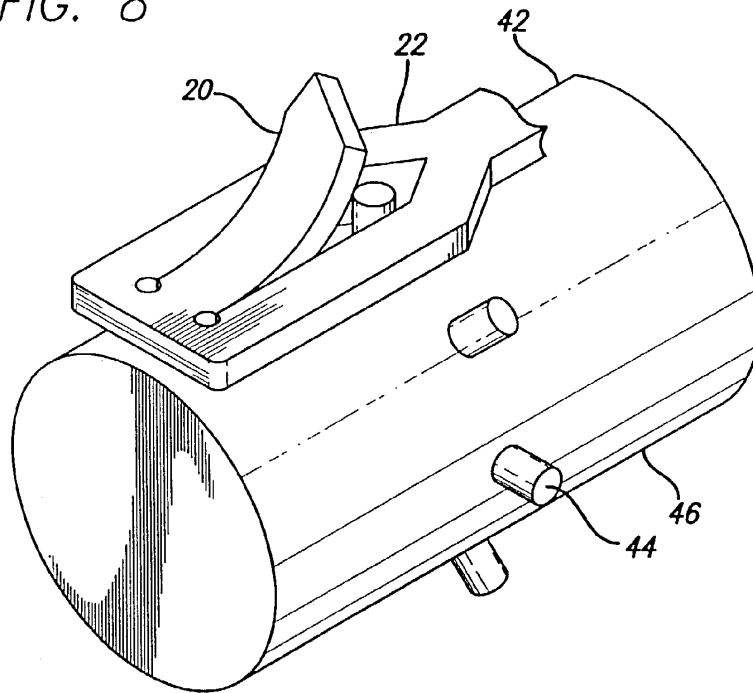


FIG. 9

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# HOOK FOR ATTACHING TO A CORPOREAL LUMEN AND METHOD OF MANUFACTURING

## CROSS REFERENCES TO CO-PENDING APPLICATIONS

This application is a Continuation of application Ser. No. 09/547,822, filed Apr. 11, 2000, now U.S. Pat. No. 6,517,573.

## BACKGROUND OF THE INVENTION

This invention relates to an attachment element for fixation to corporeal tissue and a method of manufacturing the same. Such an attachment element may be used to attach endoluminal prosthesis within arteries, veins and similar lumens. As such, the attachment element would be capable of intraluminal delivery.

A variety of endoluminal prosthesis currently exist which require fixation within corporeal lumens. Examples of such are grafts and stents. Grafts are artificial lumens which replace the natural lumen or reside within the natural lumen and isolate the natural tissue from blood flow.

Stents are semi-rigid tubular structures which may be used to maintain the patency of natural lumens or grafts. By providing scaffolding for the lumen, stents prevent collapse and occlusion. Stents are typically formed either by winding wire into a tubular structure or removing material from a solid tube.

Prior art grafts and stents have described the use of hooks to improve fixation of the prosthesis. These hooks were typically formed of bent wire attached to the prosthesis. The prior art also teaches integrally formed hooks on the prosthesis. These integral hooks are formed to be axially aligned with the prosthesis prior to deployment and forced outwardly upon intraluminal deployment.

What has not been taught by the prior art and was heretofore unknown is an integrally-formed, outwardly pre-disposed hook for attaching to a corporeal lumen. The present invention satisfies that need.

## SUMMARY OF THE INVENTION

Briefly and in general terms, the present invention embodies an attachment or anchoring element (ie., protrusion, hook, barb) for fastening to corporeal tissues and a method of manufacturing the same. The attachment or anchoring element is formed as an integral portion of a metallic frame and has a preset outward bend or curve. The attachment or anchoring element is generally comprised of an elongated member and a pointed end. The pointed end is configured to impinge upon and possibly pierce corporeal tissue, plaque or other debris or disease.

In general, the present invention provides an improved attachment or anchoring element (which will be referred to herein as a hook for convenience) for fixation of endoluminal prosthesis. As such, the hook is configured for intraluminal delivery within a catheter or capsule. The hook and endoluminal prosthesis may then be delivered to a diseased or damaged portion of a corporeal lumen such as an artery or vein. Once delivered the hook may be compressed into or pierce the interior surface of the lumen. When compressed in such a fashion, the hook and prosthesis are securely fastened to the corporeal lumen.

There exists a variety of endoluminal prostheses which would benefit from the superior fixation provided by a hook

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which embodies the features of the present invention. Once such device, an abdominal aortic graft is used to treat abdominal aortic aneurysms. Such treatment requires the intraluminal delivery of the graft across the aneurysm. Once delivered the graft must be firmly attached to the surrounding tissue of the abdominal aorta. The present invention, in one possible embodiment, may be configured to provide secure leak-proof fixation for abdominal aortic grafts.

The hook may be formed integrally with the endoluminal prosthesis to be secured. It may also be formed separately and attached to the prosthesis by a variety of well-known means. The hook is typically formed from a metallic frame. This frame could be separate from the host prosthesis or be a portion thereof.

The hook is formed by cutting narrow incisions in the frame. These incisions define the elongated member and the pointed end. Laser-cutting is a well-known method of making such incisions. Once the hook is cut it can be bent outwardly such that the pointed end faces the direction in which the corporeal tissue will lie. This bend or curve in the hook may be permanently set by heating. Once set, the hook may be pressed back into the frame and the hook will spring back into the bent position when released due to its resilient nature.

There are a variety of configurations for the hook which are embodied in the present invention. The elongated member may have a constant cross-section throughout its length. It may also have a reducing cross-section near the pointed end. The pointed end may include one or more barbs. One configuration includes a single barb on either side of the pointed end, forming an arrowhead configuration. The pointed end may also be sharpened to further ensure fixation. Multiple hooks may be formed within a single frame. It is possible to form multiple hooks from a single set of incisions. Multiple hooks in opposing directions may provide superior fixation.

Other features and advantages of the present invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example the principles of the invention.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of one embodiment of the hook and frame.

FIG. 2 is a side view of the hook and frame piercing a corporeal lumen wall.

FIG. 3 is a side view of the hook and frame with the hook compressed.

FIG. 4 is a partial front view of multiple hook and frame combinations formed integrally with a typical endoluminal prosthesis.

FIG. 5 is a perspective view of multiple hook and frame combinations attached to a typical endoluminal prosthesis.

FIG. 6 is a perspective view of an endoprosthesis having medial hooks.

FIG. 7A is a front view of a first embodiment of the hook and frame.

FIG. 7B is a front view of a second embodiment of the hook and frame.

FIG. 7C is a front view of a third embodiment of the hook and frame.

FIG. 7D is a front view of a fourth embodiment of the hook and frame.

FIG. 7E is a front view of a fifth embodiment having multiple hooks on a single frame.

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FIG. 7F is a side view of a hook having a decreasing radius of curvature;

FIG. 8 is a perspective view of a first embodiment of a mandrel assembly for bending the hook.

FIG. 9 is a partial cross-sectional view of a second embodiment of the mandrel assembly and a hook and frame.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in FIGS. 1 and 2, the invention may be embodied as a hook 20 formed integrally within a frame 22. The hook 20 is comprised of an elongated member 24 and a pointed end 26. The hook 20 may be bent or curved such that the pointed end 26 extends out of the frame 22.

The hook 20 and frame 22 are configured to secure themselves to corporeal tissue. The pointed end 26 may be compressed onto corporeal tissue such that it impinges into or possibly pierces the tissue. With the curve as shown in FIG. 2, force applied downward on the frame 22 causes the hook 20 to embed into the tissue. A preferred configuration is sized to be delivered intraluminally and attach to the inside of a blood vessel. Another possibility is to configure the hook 20 and frame 22 to attach to an artificial lumen such as an endoluminal graft.

In the compressed configuration, as depicted in FIG. 3, the hook 20 is preferably compressed until the hook 20 is within the bounds or circumference of the frame 22. In this manner, the combination of the hook 20 and frame 22 forms a nearly flat profile. Since the hook 20 has been deformed into a preset bend, the pointed end 26 may still extend a short distance out from the frame 22. Furthermore, due to the preset bend, the elongated member 24 may extend a short distance out of the frame 22 in the opposite direction from the pointed end 26. This compression of the hook 20 provides a very narrow cross section which facilitates loading the device into a catheter for delivery.

The hook 20 and frame 22 may be attached to or formed as part of an intraluminal endoprosthesis 28. This configuration is depicted in FIG. 4. When so attached, the function of the hook 20 and frame 22 is to secure the endoprosthesis 28 within a vascular lumen. This may be accomplished by forming or attaching the frame 22 on the endoprosthesis such that the hook 20 will embed itself into the lumen when the endoprosthesis 28 is deployed. It is to be recognized that although FIG. 4 shows hooks 20 configured at a superior end of the endoprosthesis 28, hooks 20 can also be incorporated into an inferior end of the device.

The hook 20 and frame 22 may also form part of an attachment device 29 for a graft 30. This configuration is shown in FIG. 5. Such an arrangement may be attached to a superior end as well as inferior ends (not shown) of the graft 30. Additionally, the attachment device 29 may be affixed longitudinally separated from the graft 30 or may be attached to inside or outside surfaces thereof. The attachment device 29 expands the hook 20 into the vessel wall. The combined attachment forces of the imbedded hook 20 and the expanded attachment system 29 provide stable fixation of the endoluminal graft 30 within the vessel.

There exists a variety of devices that fit within the definitions of an intraluminal endoprosthesis 28 and a graft 30. Most of these devices would benefit from the use of the securing devices defined herein. As shown, the same may form part of grafts which primarily replace the natural lumens or isolate them from the blood flow. Stents, which primarily ensure the patency of a lumen by resisting collapse

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and occlusion, can also benefit from the present invention as would implantable blood clot filters such as those often put in the vena cava.

The addition of the frame 22 and hook 20 of the present invention to existing grafts, stents and filters would provide such devices with superior fixation capability. For grafts the present invention will provide the additional benefit of leak-proof sealing of the graft to the blood vessel.

Endoluminal devices are typically collapsed for intraluminal delivery. Upon delivery to the desired location within the corporeal lumen, these devices are re-expanded. This re-expanding is accomplished in a number of ways. Balloon expansion requires the use of an angioplasty-type balloon catheter, which expands a device located about the balloon. Self-expansion uses the spring forces or super-elastic properties of the compressed device to expand outwardly once released. Shape memory metals have also been used in endoluminal devices to expand upon the addition of energy or chemicals. The expansion forces of any of these methods are sufficient to embed the appropriately placed hook 20 into a corporeal lumen. The frame 22 and hook 20 may be attached to the device such that the hook 20 is disposed radially outwardly from the device. As the device further expands radially outwardly the hook 20 is driven into the tissue of the corporeal lumen. Using several hook 20 and frame 22 combinations around the perimeter of the device ensures the most secure attachment.

Another method of securing the hook 20 allows attachment without relying upon expansion forces. The hook 20 may be impinged into the corporeal lumen by translating the hook 20 and frame 22 axially. Since the elongated member 24 is bent outward as it extends toward the pointed end 26, translating the hook 20 in the opposite direction of the elongated member's extension will force the pointed end 26 deeper into the corporeal lumen. Implanting the hook 20 and frame 22 in a position such that the axial forces of the blood flow are in this same direction will help secure the device over an extended period.

The frame 22 may be a separate device or may be a portion of the endoluminal device to which the hook 20 and frame 22 are a part. The frame 22 may be a small flat plate. Additionally since many endoluminal devices are formed from tubes, the frame 22 may be a portion thereof. That is, the frame 22 may be curved. Within the Figures, the frame 22 is depicted as a small roughly rectangular element with a connection 36 at one end. However, the frame 22 may be of any size or shape, or the frame 22 may be indistinguishable from the components of the endoluminal device from which the frame 22 is formed.

The hook 20 and frame 22 are typically formed of metal. Biocompatible stainless steel and Nitinol (Nickel Titanium Alloy), are particularly suited for this purpose. More exotic materials such as ceramics and plastics may also perform adequately.

The hook 20 may be formed in the frame 22 by first cutting incisions 40 into the frame 22. Preferably these incisions 40 are cut in such a manner as to remove the smallest amount of material from the frame 22 and hook 20, while still allowing for stress relief and freedom of movement of the hook. This preferred method leaves the hook 20 bounded on three sides by a narrow incision 40. This cutting forms the elongated member 24 and the pointed end 26. Laser cutting is a process known in the art which is preferred for making these incisions. To relieve the stresses caused by bending, additional material may be removed at the end of the incisions 40 in the form of cut-outs 52 (shown in FIG. 1).

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With reference to FIG. 6, it is to be noted that it is also contemplated that an endoprosthesis 28 of the present invention can embody hooks 20 that are located medial the ends 29, 31 of the endoprosthesis 28. In such an arrangement, the hooks 20 can be positioned at a junction 33 between adjacent struts of adjacent cells 35 that define the endoprosthesis 28. It is to be recognized that although FIG. 9 shows a hook 20 positioned at each junction 33, for certain applications, fewer hooks 20 may be desirable.

Varying the configurations of the incisions 40 made in the frame 22 will provide a variety of configurations of the hook 20. As depicted in FIG. 7A the simplest configuration may be to cut parallel incisions 40 with a pointed end 26 which forms a constant cross-section elongated member 24 with a simple point.

Another configuration depicted in FIG. 7B has non-parallel incisions 40 which narrow towards the pointed end 26. This produces an elongated member with a cross-section which reduces toward the pointed end 26. The reduction in cross-section allows a decreasing bend radius near the pointed end 26 (See FIG. 7F). In this manner the pointed end may be pointed outwardly more towards the perpendicular which aids in impinging the corporeal tissue.

Another configuration, depicted in FIG. 7C, includes barbs 38 on the pointed end 26. With two such barbs 38 the pointed end has an arrowhead configuration. These barbs 38 may help secure the hook within the corporeal lumen.

Combining configurations, as depicted in FIG. 7D, produces a narrowing elongated member 24 with barbs 38. Such a configuration could combine the advantages of a decreasing bend radius with that of a barbed pointed end 26 (See FIG. 7F).

Another configuration, depicted in FIG. 7E, creates a plurality of hooks 20 from the same incisions 40. This could form hooks 20 which project in opposing directions. Such a configuration would provide superior resistance to radial and axial loads from the corporeal lumen and blood flow.

The pointed end 26 of each of these configurations may be sharpened to improve its ability to pierce the corporeal lumen. Material may be removed from either or both the lumen-facing or frame-facing sides of the pointed end 26 to produce a sharper point.

The preferred method of manufacturing the hook 20 and frame 22 includes cutting the hook 20 out of the frame 22 using narrow incisions 40. Several methods of making such incisions 40 in metal are well known. Possible examples are laser cutter, photo-etching and chemical etching.

Once the hook 20 is cut into the frame 22, it may be bent away from the frame 22. This may be accomplished manually by using tweezers to force the pointed end 26 of the hook 20 away from the frame 22. If the hook 20 and frame 22 are formed as part of an endoluminal device, the device may be mounted on a mandrel 42 with pins 44 or similar means to force the pointed end 25 of the hook 20 away from the frame 22.

As depicted in FIG. 8, the mandrel 42 is preferably configured as a cylindrical shaft with pins 44 appropriately spaced about the circumference of the shaft. A frame 22 may be pressed against the shaft 46 such that a pin 44 forces the hook 20 outwardly. This configuration can be maintained while the hook 20 is heat sent to be permanently predisposed with an outward curve. Another preferred configuration for the mandrel, as depicted in FIG. 9, includes a cylindrical shaft 46, a convex outer ring 48 and a concave outer ring 50. A curved gap between the outer rings forces the hook 20 into a predetermined bend. This configuration of shaft and rings may be clamped together for heat setting.

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After bending, the hook 20 may be permanently-deformed into the curved configuration by heat setting the material. For a Nitinol hook 20 and frame 22 combination heating at 550° C. for ten minutes is sufficient. A ceramic or plastic hook 20 and frame 22 combination might be formed in a bent configuration.

With a permanently deformed hook 20, the hook 20 may still be compressed into alignment with the frame 22 without losing the preset curve. Thus, the hook 20 may be compressed into the frame for intraluminal low-profile delivery, and then deployed in the curved configuration by releasing. This is a significant advantage in producing a fixation device small enough to be delivered intraluminally.

It will be apparent from the foregoing that, while particular forms of the invention have been illustrated and described, various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

What is claimed is:

1. A mechanism for securing an endoprosthesis within a corporeal lumen, the mechanism comprising:

a frame element with incisions formed therein, the frame element having a substantially tubular shape and lacking concentrically overlapping structure;

the incisions forming an elongated member having a pointed end, the elongated member being bounded by the frame element; and

the elongated member bent away from said frame element wherein the elongate member has a permanent curve.

2. The mechanism of claim 1, wherein the elongated member has parallel straight sides defining a constant width.

3. The mechanism of claim 1, wherein the elongated member has non-parallel straight sides defining a narrowing width towards the pointed end.

4. The mechanism of claim 1, wherein the elongated member is resilient so as to be compressed into a position within the circumference of the frame element when constrained and to extend outside the circumference of the frame element when unconstrained.

5. The mechanism of claim 1, wherein the elongated member has a permanent constant radius curve.

6. The mechanism of claim 1, wherein the elongated member has a permanent curve of decreasing radius.

7. The mechanism of claim 1, wherein the pointed end includes at least one barb.

8. The mechanism of claim 1, wherein the pointed end is sharpened.

9. The mechanism of claim 1, wherein the mechanism is integrally formed into an endoluminal prosthesis.

10. A connector for fastening a device to corporeal tissues, said connector comprising:

a substantially tubular body lacking concentrically overlapping structure;

a hook having two sides and a point and being bounded by the tubular body;

said sides and said point defined by narrow slits in the connector; and

said hook having a permanent bend that forms a permanent curve.

11. The connector of claim 10, wherein the sides of the hook are parallel and straight and define a constant width.

12. The connector of claim 10, wherein the sides of the hook are non-parallel and straight and define a narrowing width towards the point.

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13. The connector of claim 10, wherein the hook forms a permanent constant radius curve.

14. The connector of claim 10, wherein the hook forms a permanent curve of decreasing radius.

15. The connector of claim 10, wherein the point is formed in an arrowhead configuration.

16. An endoluminal prosthesis, comprising:  
a substantially tubular frame element, the frame element lacking concentrically overlapping structure; and

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at least one protrusion cut out of said frame element having a resiliently flexible bend formed therein, wherein the at least one protrusion has a permanent curve the at least one protrusion being bounded by the frame element and the at least one protrusion having a pointed end.

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## **CERTIFICATE OF SERVICE**

I certify that, on September 25, 2015, copies of the foregoing documents were served via email on counsel for LifePort at the following addresses:

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### **CERTIFICATE OF COMPLIANCE**

Counsel for appellants Medtronic Inc. and Medtronic Vascular Inc. certifies that this brief complies with the type-volume limitation of Rule 32(a)(7)(B)(i) of the Federal Rules of Appellate Procedure. The brief contains 7,932 words, excluding the parts of the brief exempted by Rule 32(a)(7)(B)(iii) of the Federal Rules of Appellate Procedure, as computed by the word count feature of Microsoft Word.

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